

BMJ Open Effectiveness of laparoscopic niche resection versus expectant management in patients with unexplained infertility and a large uterine caesarean scar defect (uterine niche): protocol for a randomised controlled trial (the LAPRES study)

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ABSTRACT

Introduction A uterine niche is a defect at the site of the uterine caesarean scar that is associated with gynaecological symptoms and infertility. Promising results are reported in cohort studies after a laparoscopic niche resection concerning reduction of gynaecological symptoms in relation to baseline and concerning pregnancy outcomes. However, randomised controlled trials to study the effect of a laparoscopic niche resection on reproductive outcomes in infertile women are lacking. This study will answer the question if laparoscopic niche resection in comparison to expectant management improves reproductive outcomes in infertile women with a large uterine niche.

Methods and analysis The LAPRES study is a randomised, non-blinded, controlled trial, including 200 infertile women with a total follow-up of 2 years. Women with the presence of a large niche in the uterine caesarean scar and unexplained infertility of at least 1 year or failed IVF will be randomly allocated to a laparoscopic niche resection within 6 weeks or to expectant management for at least 9 months. A large niche is defined as a niche with a depth of >50% of the myometrial thickness and a residual myometrium of ≤3 mm on transvaginal ultrasound. Those receiving expectant management will be allowed to receive fertility therapies, including assisted reproductive techniques, if indicated. The primary outcome is time to ongoing pregnancy, defined as a viable intrauterine pregnancy at 12 weeks' gestation. Secondary outcome measures are time to conception leading to a live birth, other pregnancy outcomes, received fertility therapies after randomisation, menstruation characteristics, patient satisfaction, quality of life, additional interventions, and surgical and ultrasound outcomes (intervention group). Questionnaires will be filled out at baseline, 6, 12 and 24 months after randomisation. Ultrasound evaluation will be performed at baseline and at 3 months after surgery.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This study is a randomised controlled trial to evaluate the effect of laparoscopic niche resection in comparison to expectant management on reproductive outcomes in infertile women with a large uterine niche.
- ⇒ In line with the Idea, Development, Exploration, Assessment and Long-term study framework, was the trial designed after optimisation of the surgical procedure and completion of the learning curve.
- ⇒ The trial is large and powered to assess time to ongoing pregnancy.
- ⇒ Laparoscopic niche resection is in the Netherlands currently not offered as a part of usual care, which reduces the risk on selection bias.
- ⇒ It is an open-label trial, which may affect the outcomes reported by the patients.

Ethics and dissemination The study protocol was approved by the medical ethics committee of the Amsterdam University Medical Centre. (Ref. No. 2017.030). Participants will sign a written informed consent before participation. The results of this study will be submitted to a peer-reviewed journal for publication. Trial registration number: Dutch Trial Register (ref. no. NL6350 <http://www.trialregister.nl>).

INTRODUCTION

Caesarean sections are rising worldwide.¹ The increasing caesarean section rate has raised an interest in the potential long-term sequelae of caesarean scarring. A uterine niche is a defect in the myometrium at the uterine caesarean section scar site; the phenomenon has been described frequently in recent

years.^{2–6} A uterine niche is formally defined by the international Niche Taskforce as ‘an indentation at the site of the caesarean scar with a depth of at least 2 mm’, visible by means of transvaginal ultrasound (TVUS).⁷ Previous studies have shown that, in approximately 50%–60% of women with a history of a caesarean section, a niche can be visualised during sonohysterography.^{2,8,9} Uterine niches are associated with gynaecological symptoms such as postmenstrual spotting, dysmenorrhoea and chronic pelvic pain.^{2–4,9,10}

A uterine niche may also reduce fertility.^{11–14} A meta-analysis reported that a caesarean section on average reduced the probability of a subsequent pregnancy by 10% (relative risk, RR 0.91; 95% CI 0.87 to 0.95), relative to a vaginal delivery.¹⁵ None of the studies included in this meta-analysis evaluated the relationship between subsequent fertility and the presence of a uterine niche. Theoretically, the accumulation of blood, mucus and fluid in the niche and uterus may impair the penetration of sperm cells and the implantation of embryos.^{9,16,17} Sometimes, when combined with an extremely retroverted uterus, a (large) niche may hamper the insertion of an insemination or embryo transfer catheter.¹⁷ A recent study including 1307 women undergoing their first IVF cycle reported significantly lower live birth rate in women with a previous CS compared with women with a previous vaginal delivery (OR 0.63, 95% CI 0.45 to 0.87).¹² Also, in this study, the presence of a niche was not always reported. A recent large prospective cohort study (n=4879) that evaluated the effect of the presence of a niche on reproductive outcomes after single embryo transfer and that corrected for potential confounders such as age, body mass index, fresh or frozen-thawed cycle, the stage of embryo at transfer and endometrial thickness, showed a significant lower live birth rate and higher miscarriage rate in women with a niche compared with women without a niche (aOR 0.61, 95% CI 0.47 to 0.78 and aOR 1.41, 95% CI 1.03 to 1.9). The differences in live birth rate were even larger if the presence of a large niche was compared with the presence of a small niche (aOR 0.42, 95% CI 0.20 to 0.90).¹⁴ These study results indicate an intermediate role of a niche in the lower pregnancy and live birth rates after a CS compared with a vaginal delivery.

In the past 15 years, several innovative surgical procedures have been developed to treat niche-related symptoms.^{18–27} Laparoscopic treatment was first described in 2003.²⁸ A hysteroscopic niche resection is effective in reducing spotting symptoms in women with small niches, but does not restore the anatomy.²⁹ A laparoscopic or vaginal niche resection aims to reduce symptoms, restore the anatomy and increase the thickness of the residual myometrium (see figure 1A,B). The latter procedures are suitable for women with large niches with thin residual myometrium.²⁴

Studies that evaluated the effect of various surgical interventions have limited sample size and are all single armed without a comparator.^{18,22,25,26} Recently, we reported a large prospective cohort study, in which promising fertility

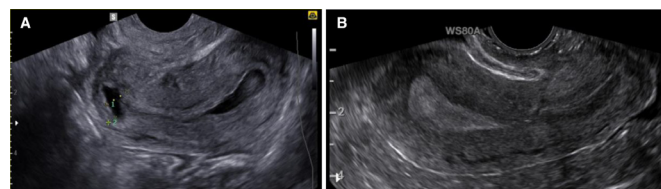


Figure 1 Image of a niche in midsagittal plane using transvaginal ultrasound before (A) and after (B) laparoscopic niche resection in the same women. (A) Extremely retroverted uterus and large niche with intrauterine fluid accumulation in niche and uterine cavity; (image after laparoscopic niche resection. Thickness of the residual myometrium increased and the position of the uterus changed from retroverted (A) to anteverted (B).

and obstetric outcomes were observed in 133 women with a wish to conceive and who underwent laparoscopic resections of large and symptomatic uterine niches. Among these women 88 (66.2%) had infertility of whom 58 (43.6%) had previous failed ART and 45 (33.8%) had an active wish to conceive but without proven infertility yet. The majority of women (62%) conceived following laparoscopic niche resection with a median interval of 3 months after contraception withdrawal (Vissers *et al* 2023, submitted). Despite the promising results, it is too early to implement laparoscopic niche resection in daily practice as a means to improve reproductive outcomes. According to the principles of the IDEAL (Idea, Development, Exploration, Assessment and Long-term study) framework, a randomised controlled trial (RCT) the next step after optimising outcomes and studying the effect of a new technique in previous cohort studies.^{30,31}

In the current study, we aim to compare the effect of a laparoscopic uterine niche resection with expectant management, for time to ongoing pregnancy and other reproductive outcomes in women with large niches in combination with (1) unexplained infertility for at least 1 year or (2) failed IVF or (3) problems during fertility therapy, such as intrauterine accumulation of fluid and/or technical problems to insert a catheter.

MATERIALS AND ANALYSIS

Design

The LAPRES study is a single-centre non-blinded RCT, performed in a tertiary referral centre in Amsterdam, the Netherlands, with a total follow-up of 2 years.

Participants and eligibility criteria

Women are eligible if a large uterine niche (defined as niche with a depth of >50% of the myometrial thickness and a residual myometrial thickness (RMT) ≤3 mm) is observed and if they have at least one of the following problems: (1) unexplained infertility for at least 1 year, (2) failed IVF or (3) problems during fertility therapy, such as intrauterine accumulation of fluid and/or technical problems to insert an intrauterine or embryo transfer catheter. Unexplained infertility was defined as: at least

12 months unprotected intercourse or self-insemination without contraception, regular ovulatory cycle at least one-sided tubal patency (established according to local protocol) and no male factor. Exclusion criteria are pregnancy, age <18 years, insufficient understanding of the Dutch or English language, contraindications for general anaesthesia, a (suspected) malignancy, uterine or cervical polyps, submucosal fibroids, atypical endometrial cells, cervical dysplasia, cervical or pelvic infection or an hydrosalpinx.

Recruitment and randomisation

Before study entry, the uterus and the uterine niche will be evaluated by means of transvaginal sonography. We will use a standardised protocol for the sonographic uterine and niche evaluation.⁷ Additionally, a pap smear will be taken if indicated or when not recently performed to exclude cervical dysplasia.

Eligible patients will be informed by one of the gynaecologists about the aims, methods, design, benefits and possible disadvantages of the laparoscopic niche resection, as a basis for informed consent (online supplemental appendix A). The informed consent form must be signed before involvement in any study-related activity. After written informed consent has been obtained, eligible women will be randomly assigned to the laparoscopic niche resection group or the expectant management group for at least 9 months. Randomisation will be blinded and managed using the research survey web-based application, which assigns a computer-generated random number to each participant. We will use a permuted block design. All women that decline to participate will be registered anonymously in order to record the number and reason for refusal. Subjects will be able to leave the study at any time and for any reason without any consequences. If women decline to participate, they are offered usual care, which does not include a laparoscopic niche resection.

Intervention (laparoscopic niche resection)

The patients assigned to the laparoscopic niche resection group will undergo a procedure under general anaesthesia in lithotomy position. Full details of the surgical procedure were published previously in our paper on short-term outcomes³² and in a step-by-step tutorial.³³ In short: the laparoscopic niche resection is continuously guided by hysteroscopy. Adhesions between the uterus and bladder or between the uterus and the abdominal wall will be lysed and the bladder will be dissected from the anterior wall of the uterus and cervix. Due to the thin myometrium overlying the niche, the niche can be transilluminated with the hysteroscopic light to be visualised laparoscopically. The thin part of the niche and all fibrotic tissue will be resected. The uterotomy will be closed using at least four full-thickness single sutures (1.0 multifilament) with sliding knots that include the entire uterine wall and the endometrium. One double inverted mattress suture will be placed across the closed wound to

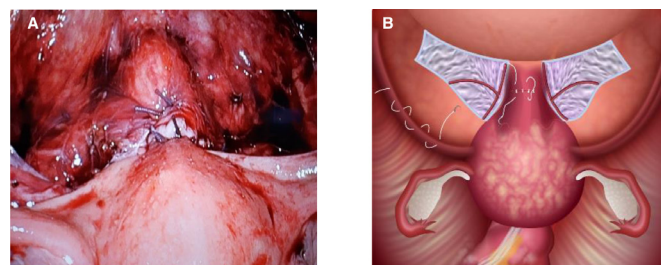


Figure 2 Double layer full thickness closing of the uterus with single sliding knots. (A) First layer of sliding knots. (B) Second layer of knots and suspension of the round ligaments (Baldi anterior).

strengthen the wound and ease the tension on the first layer of sutures. If the uterus is (extremely) retroverted even after uterine repair, the round ligaments will additionally be shortened (Baldi anterior) using two continuous running sutures (2.0 multifilament) (see figure 2). An adhesion barrier (Hyalobarrier, Nordic Pharma) will be applied after uterine closure. The anatomical result of niche closure will be evaluated by hysteroscopy at the end of the procedure. To illustrate the procedure, we included a video.³³ Women were advised to use contraception in the first 6 months following niche resection to allow uterine healing prior to subsequent pregnancy.

Control group

The control group will receive usual care according to the local protocol of the referring centre for at least 9 months which means no additional surgical intervention during this period. However, patients are allowed to become pregnant and to receive fertility therapies if indicated, this includes IUI or IVF dependent on their previous received fertility therapies at inclusion. In the intervention group, patients are also allowed to receive fertility therapies if indicated after the intervention from 6 months onwards. All additional therapies received, both by intervention group members and by control group members, will be registered. Any member of the control group who has not become pregnant after 9 months will be given the opportunity to undergo a laparoscopic niche resection.

Evaluation

Patients who are referred to our tertiary referral centre because of a niche and/or related symptoms will be evaluated at our outpatient clinic by trained niche experts as a part of the standard care provision. All such patients will receive a standardised TVUS evaluation of the pelvis, ovaries and uterus. Uterine pathology will be evaluated according to the MUSA guidelines^{34 35} double endometrial thickness, position of the uterus and presence of sliding sign between bladder and bowels will be documented. In case of suspected adhesions, we will measure the total length of the non-sliding area between the uterus and bladder. The presence of deep endometriosis will also be evaluated.

Niches will be evaluated at baseline in all groups and at 3 months after surgery, in accordance with the international expert recommendations on the evaluation and reporting of niches.^{7 36} The position of the uterus (anteversion, straight, retroversion or extreme retroversion (broken uterus) and presence of a niche (defined as an indentation of at least 2 mm) and fluid accumulation in the niche or uterine cavity will be documented. Gel will be introduced if intrauterine fluid is not present in line with the recommendations of international experts.⁷ The length, depth, width and volume of the niche, RMT and adjacent myometrium thickness (AMT), branches of the niche visible in the sagittal and/or transversal plane and distance between the niche and the vesicovaginal fold will be measured. In addition, the presence of any large niches (RMT < 50% of AMT, RMT < 3 mm) will be documented. All sonographic examiners will undertake the online tutorial (www.nichelearning.online).³⁶ This learning module is based on the results of a Delphi procedure involving an international group of niche experts.⁷

Study procedures

The study will be performed in accordance with Good Clinical Practice (GCP) guidelines. Evaluation of eligibility, niche evaluation and counselling will be performed by physicians with extensive experience in those activities. The surgical interventions will be performed in our centre by at least one of the two experienced gynaecologists (JH and WJKH), each of whom has previously performed more than a hundred laparoscopic niche resections.

Patient and public involvement

In 2017, two focus group discussions (N=8 and 5) were conducted. Participants were Dutch patients with a large niche, who were scheduled for surgical treatment for their symptoms. Abnormal uterine bleeding, subfertility, sexual functioning, abdominal pain and self-esteem were themes prioritised by participants, and therefore, taken into account in our study protocol and also outcome parameters were based on input of these focus group discussions.³⁷

Outcome measures

Primary outcome measure

The primary outcome measure is time to ongoing pregnancy, defined as a viable intrauterine pregnancy at twelve weeks gestation.

Secondary outcome measures

The key secondary outcome is time to pregnancy leading to a live birth.

Other secondary outcome measures are

- ▶ Fertility and pregnancy outcomes: live birth, pregnancy rate, clinical pregnancy rate, ongoing pregnancy rate, miscarriage rate, ectopic pregnancy, pregnancy outcomes including gestational age at delivery, percentage of patients with term delivery, mode of delivery, adverse events during pregnancy and delivery.
- ▶ Received fertility therapies after randomisation

- ▶ Menstruation characteristics: cycle length, number of days during menstruation, postmenstrual spotting (yes or no) and number of spotting days, pain during menstruation (Verbal Rating Score: VRS), abdominal pain on non-menstruating days (VRS), urinary symptoms (shortlist of SFFI), quality of life based on Short-Form-36 (Aaronson *et al*, 1998),³⁸ EQ-5D-5L (The EuroQol Group (1990))³⁹; 'EuroQol—a new facility for the measurement of health-related quality of life', 1990) and patients self-reported satisfaction (Likert scale)
- ▶ Perioperative outcomes (intervention group): surgery time, blood loss during surgery, perioperative and postoperative complications (Clavien-Dindo classification),⁴⁰ hysteroscopic result immediately after laparoscopic niche resection, extent of adhesions, subjective characteristics such as surgeon satisfaction and difficulty of the procedure.
- ▶ Additional interventions: applied medical and/or surgical interventions because of gynaecological symptoms will be assessed at 6 and 12 months and 2 years follow-up.
- ▶ TVUS evaluation will be performed 3 months after a laparoscopic niche resection: presence of a niche, length, depth and width of the niche, RMT, AMT, accumulation of intrauterine fluid, presence of sliding sign or suspected adhesions between the bladder and uterus will be reported in the same way as at baseline.

Data collection and management

Collection of baseline characteristics and patient-reported outcomes

Baseline characteristics will be collected by means of a digital questionnaire including SF-36 domain scores, EuroQol scores and FSFI scores sent to participants' email addresses. At 6, 12 and 24 months follow-up, further digital questionnaires will be sent to participants to assess the primary and secondary outcomes (figure 3, flow chart). Reminders for all questionnaires will be sent every 2 weeks; up to three reminders will be sent in each instance. If a participant does not respond to the reminders, a research nurse will call the participant. The gynaecologist, the research nurse or the researcher will also fill out a baseline eCRF (electronic case report form).

Intraoperative data

Immediately after the niche resection, the surgeon will be asked to register relevant items regarding the procedure in an eCRF. These items include: surgery time, blood loss during surgery, major and minor perioperative complications, hysteroscopic result immediately after laparoscopic niche resection, extent of adhesions and distance, subjective characteristics such as surgeon satisfaction and difficulty of the procedure.

Niche evaluation

All patients in the intervention group will undergo TVUS 3 months after the laparoscopic niche resection to register all uterine and niche features.

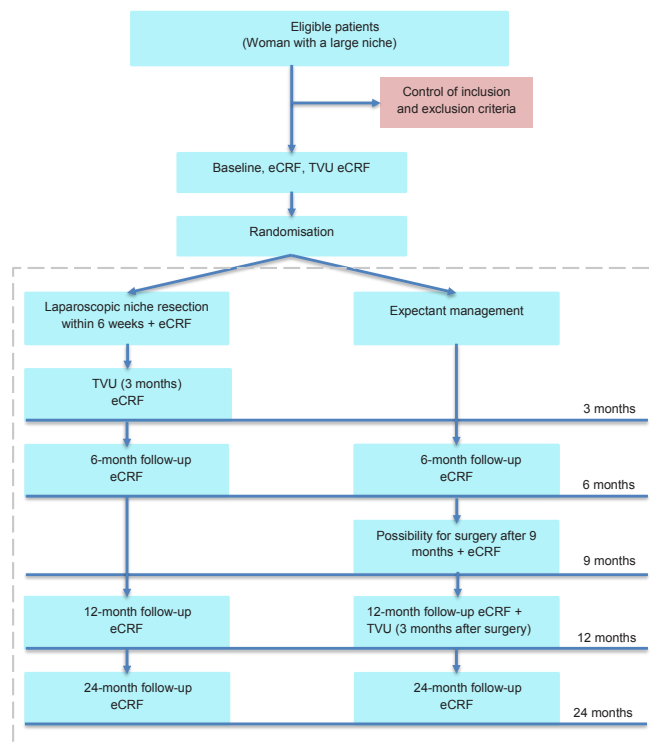


Figure 3 LAPRES study flow chart.

Serious adverse events

All serious adverse events (SAEs) will be reported to the medical ethics committee (MEC) by line listing yearly. Life-threatening SAEs or an event that leads to death will be reported to the MEC immediately. All SAEs will be followed until they have abated, until a stable situation has been reached or the patient was discharged.

Confidentiality and data security

All participating researchers receive a login name and password to gain access to researchsurvey.nl, a web-secured randomisation database. Randomisation is performed pseudoanonymously with only the initials and year of birth of the participants. Linking personal data to the study number can only be performed by the trial coordinator. Written informed consent forms are stored in a lockable room. All forms and data will be archived for 15 years in the participating centres.

Statistical analysis

Data will be analysed in accordance with the intention-to-treat principle with a sensitivity analysis according to the per-protocol principle. Baseline characteristics will be presented using percentages, means with SD and 95% CI or medians with IQRs, as appropriate. We will calculate RRs and 95% CIs for all pregnancy outcomes. To study time to ongoing pregnancy, we will construct Kaplan-Meier curves and use the log rank test to compare the treatment groups. In addition, we will estimate the marginal HR with 95% CI using a Cox proportional hazards model. The difference between the two groups in terms of all continuous variables will be analysed

using the Mann-Whitney U test for non-parametric data (total number of postmenstrual spotting days during one menstrual cycle, days of spotting at the end of the menstruation, days of intermenstrual spotting, dysmenorrhoea, experienced discomfort due to spotting, niche depth and RMT). Quality of life measures over time will be analysed using linear mixed models using random intercepts for individual women and time point. Fisher's exact test will be used for the rare binary data, such as the presence of (midcycle) intrauterine fluid and the presence of pain during micturition. Satisfaction with the randomised treatment will be recoded into a binary outcome using 'dissatisfied' (combining dissatisfied, very dissatisfied and neutral) or 'satisfied' (combining satisfied and very satisfied) and will be analysed using the χ^2 test.

Predefined subgroup analyses

We aim to investigate effect modification of the intervention by the prognosis of individual women, as this avoids looking at many different characteristics separately.⁴¹ To conduct this, we first will develop a prognostic model on the data regressing pregnancy on the following list of a priori selected predictors in a Cox model: (1) age, (2) one versus more previous caesarean sections, (3) postmenstrual spotting complaints (yes or no), (4) presence of midcycle intrauterine fluid accumulation, (5) suspected presence of concomitant adenomyosis and/or endometriosis, (6) duration of infertility, (7) infertile before last CS and (8) previous failed IUI or IVF. Next, we will use the model to estimate the individual probability of pregnancy after 1 year (which represents their characteristics summarised in a prognosis 'score'). Finally, we will fit a new Cox model regressing pregnancy on treatment allocation, score and the interaction between the two.

For the second sensitivity analysis, we will opt for the 'cloning' methodological approach for a treatment that is started later in time: the principle is that if the treatment decision is made at some point after diagnosis, we are comparing 'strategies' to eventually treat or not rather than assigning treatment at a fixed time point as in an RCT. We start with using the data from all patients for both strategies, then will follow women over time and censored, that is, remove them from analysis when they do not adhere to their assigned strategy, which here involves receiving treatment in the expectant management 'strategy' group. For example, a woman who received laparoscopic niche resection at 9 months after randomisation provided data on expectant management for both strategy groups during the first 9 months, was followed after laparoscopic niche resection in the treatment strategy group but censored at the time of laparoscopic niche resection in the expectant management group. Finally, we will fit adjusted (weighted) Kaplan-Meier curves for both groups and conduct a log-rank test to compare the curves. What we obtain is the absolute chance of a live birth over time for both strategies.

Additional analyses

We plan an additional analysis of effect on the primary outcome, where we exclude women who have decided for other reasons that they do not want to become pregnant for at least a year or who had another surgical intervention including but not limited to a hysteroscopic niche resection or a laparoscopic niche resection or hysterectomy (in other centres) during the first 9 months in the expectant management group. Interim analysis will not be performed because of the long-term follow-up. Total follow-up will extend to 2 years after randomisation.

Sample size calculation

When designing this study, there were no data available on the ongoing pregnancy rates in women with a large niche. However, we did have ongoing pregnancy rates in women undergoing their first IVF cycle who had one previous CS, this was 20.1% in our centre.¹² We assumed that ongoing pregnancy rates will even be lower in women with a large niche.

In order to justify a new invasive surgical procedure, we defined that it should at least result in a doubling of the ongoing pregnancies rate. As such, we powered our study on the assumption that the ongoing PR increased from 20% to 40%. Assuming 40% pregnancies in the intervention group, 20% pregnancies in the control group, a (two sided) significance level of 0.05 and a power of 0.80, we need 82 women in each group. Because we expect a drop-out rate of 15%, we intend to include 200 patients

Ethics and dissemination

The study protocol has been approved by the medical ethics committee (MEC) of the Amsterdam University Medical Centre. (Ref. No. 2017.030). Protocol amendments will be communicated after approval by the central MEC of Amsterdam UMC. The trial has been registered in the International Clinical Trial Registry Platform (ICTRP) (Ref. No. NTR6534; <https://trialsearch.who.int/>). Eligible women will be counselled in accordance with the GCP guidelines for doctors certified according to the Basic Course on Regulations and Organisation for Clinical Researchers (BROK). Participants will sign a written informed consent before participation (online supplemental appendix A). All recommended items on the SPIRIT 2013 checklist have been addressed in this clinical trial protocol (online supplemental appendix B). The results will be communicated after final inclusion and follow-up, by means of publication in a peer-reviewed international journal and at an international conference.

Patient enrolment began in 2017. We expected completion of follow-up in 2025.

DISCUSSION

In recent years, several innovative surgical therapies have been developed to treat niche-related symptoms or to improve reproductive outcomes. Previous smaller cohort studies reported positive effects on symptoms and

reproductive outcomes after laparoscopic niche resection.^{18 22–24 32} However, given the lack of RCTs comparing the intervention with expectant management, we do not know exactly how the beneficial effect of laparoscopic niche resection compares with expectant management. The effect of laparoscopic niche resection on reproductive outcomes should be evaluated in RCTs before it is implemented in guidelines and daily practice. We hypothesise that laparoscopic niche resection will lead to better reproductive outcomes compared with expectant management in patients with a large niche and unexplained infertility or failed IVF.

Strengths and limitations

To our knowledge, this is the first RCT that evaluates the effect of laparoscopic niche resection in comparison to expectant management on reproductive outcomes in infertile women with a large uterine niche. The study was designed after the execution of a large cohort study in our centre where we optimised the procedure and completed our learning curve. (Visser *et al* 2023, submitted). This is in line with the proposed IDEAL framework for introduction and evaluation of new surgical techniques.³⁰ Additionally, this risk on selection bias is limited due to the fact that a laparoscopic niche resection in the Netherlands is currently not offered as a part of usual care. To reduce the chance of bias, randomisation will involve allocation concealment by means of a web-based randomisation programme. Given the nature of the procedure, the study cannot be blinded for the patient, which may possibly affect the outcomes reported by the patient.

We expect the study to have some limitations as well. We will not be able to study the safety (maternal and/or neonatal outcome) of vaginal delivery after a laparoscopic niche resection, because we advise the included patients as a part of our protocol to undergo an elective caesarean section at term. However, this advice can be debated. Although the thickness of the residual myometrium after a caesarean section and its change during the subsequent pregnancy is associated with the likelihood of a successful labour it is not clear what the optimal cut-off value is for a safe and successful trial of labour.⁴² In addition, the chance of uterine rupture during labour is associated with a smaller RMT.^{43–45} There is no evidence that, even with a thick residual myometrium after laparoscopic niche resection, it is safe to deliver vaginally.

Potential impact and implications

So far, given the absence of comparative studies, there is no clear evidence that proves the additional value of a laparoscopic niche resection in order to improve fertility or pregnancy outcomes. However, an increasing number of physicians offer this innovative therapy to their patients with a niche, which may potentially lead to overtreatment. The proposed study is therefore intended to provide more conclusive evidence on the additional value of a laparoscopic niche resection compared with expectant management in women with a large niche

and unexplained infertility or failed IVF. It will provide insight in effect on reproductive outcomes, in potential side effects or complications and on its effect on required fertility therapies and quality of life. These results will guide professionals on the need for uptake of this intervention in guidelines and can be used for counselling of patients with a large niche and infertility on the effect and risks of a laparoscopic niche resection.

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