HYSTEROSCOPIC CRYOMYOLYSIS FOR THE TREATMENT OF SUBMUCOSAL LEIOMYOMATA

Published: 22-04-2008
Last updated: 10-05-2024

The primary objective of this study is to evaluate the technical success, feasibility and safety of hysteroscopic US guided cryomyolysis procedure.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive neoplasms female benign
Study type	Interventional

Summary

ID

NL-OMON31767

Source
ToetsingOnline

Brief title
HCT

Condition

- Reproductive neoplasms female benign
- Obstetric and gynaecological therapeutic procedures

Synonym
cryoablation, myoma freezing

Research involving
Human

Sponsors and support

Primary sponsor: Galil Medical
Source(s) of monetary or material Support: Galil Medical

Intervention

Keyword: Ablation, Cryomyolysis, Cryotherapy, Hysteroscopy

Outcome measures

Primary outcome

1) Safety of the procedure will be assessed by incidence and severity of intra

and post procedure related adverse events (AE) up to 4 weeks post procedure.

2) Technical success and procedure feasibility will be assessed by:

o Identification of fibroid under ultrasound

o Visibility of needles under ULS

o Insertion of needles to the fibroid and positioning of the needle in the

fibroid

o Visibility of the fibroid and needle by the hysterospcope optics

o Visibility of ice ball propagation and fibroid optimal coverage

o Type of fibroid and location and impact on success rate

Secondary outcome

o Hysteroscopic cryomyolysis related pain will be measured by self reported

pain severity Visual Analogue Scale (VAS) completed by the patient prior to

discharge from hospital.

o Time (in days) to return to normal activity (reported by the patient at 4

weeks follow-up visit and recorded in the CRF).

o Average duration of post operative hospital stay.

o Evaluation of length of an average procedure.

o Physician's satisfaction from the ease and convenience of the hysteroscopic

cryoablation procedure will be documented in a satisfaction questionnaire.

Study description

Background summary

The reported literature reports promising results for the use of cryomyolysis as a minimally invasive, conservative treatment modality for uterine myomas. Thus far, most studies have used either laparoscopic guidance or MRI-guidance for the procedure.

This proposed feasibility study is looking to examine the technical success, safety and feasibility of a hysteroscopic approach for the treatment of symptomatic fibroids. This technique involves a hysteroscopically placed Galil-Medical 17-G Cryotherapy needle(s) during conventional hysteroscopy with an operative hysteroscope.

This treatment could offer several potential benefits over a laparoscopic approach or MRI guided procedure. First, a hysteroscopic procedure is associated with fewer risks than a laparoscopic procedure. No abdominal access is needed with hysteroscopy, and thus is not associated with the rare but potentially morbid complications associated with laparoscopy. Furthermore, the use of MRI has limited availability and high associated costs. Hysteroscopy is available to most gynecologists in most centers, and so could be used by many providers without significant extra training.
Most importantly, submucous myomata that comprise 10-15% of all fibroids, are the most likely fibroids to cause symptoms such as heavy uterine bleeding. These fibroids are best accessed via a hysteroscopic or transvaginal approach.

Study objective

The primary objective of this study is to evaluate the technical success, feasibility and safety of hysteroscopic US guided cryomyolysis procedure.

Study design

The procedure is planned after preparatory counseling and examinations as usual for hysteroscopic treatment of submucous myoma*s.

The procedure is performed in the operating theater under visual ultrasound guidance. See protocol 7.1

Intervention

Hysteroscopic cryomyolysis under visual ultrasound guidance

Study burden and risks

Risks:

The risks associated with hysteroscopic cryomyolysis are similar to other hysteroscopic procedures. There is a large experience with diagnostic and operative hysteroscopy in which the complication rate is in the 1-2% range. In experienced hands however the complication rate is even much lower: up to a 16 fold difference between experienced (> 1000 procedures) and less experinced (< 1000 procedures) has been reported.

* Uncommon complications associated with operative hysteroscopy include; Infection, bleeding, and uterine perforation possibly leading to injury to internal organs such as bladder, bowel and blood vessels. Additionally, there is a risk of fluid absorption as fluid is used for uterine distention during operative hysteroscopy. Weighted measuring systems and strict rules regarding fluid deficits are used in all hysteroscopic procedures making this complication extremely rare.

* Additional potential complications from the cryomyolysis include extension of the ice ball past the fibroid and uterine myometrium with the possibility of damaging adjacent organs.
* To limit this risk, the cryomyolysis is performed under ultrasound guidance to monitor the ice ball formation. The ice ball is only formed to within the fibroid, leaving a margin of safety,

* since the iceball margins reach temperature of zero which is not lethal. The cryoneedle can be manually controlled to stop the freezing process at any time.
* Intraoperative or postoperative bleeding requiring blood transfusion and/or conversion to open surgery. Bleeding occurring from the fibroid surface after extraction of the cryoneedles * refers usually to oozing which is controlled by local cauterization of the bleeding site.
* Adhesion formation may result like in any other surgical procedure but its risk is minimized by minimizing serosal surface trauma, bleeding and infection
* Thromboembolism can occur like in any other Gynecologic procedure, although the procedure does not involve manipulation of pelvic vasculature or prolonged immobility. Hysteroscopic cryomyolysis treatment will be performed under standard Thromboembolism-preventing care.
* Risks of anesthesia * may occur like in any other procedure. The risk from

anesthesia may include allergic reaction to medications which may result in serious patient injury or even death.

Potential Benefits:

Individuals participating in this study may benefit from hysteroscopic cryomyolysis in several ways:
* If successful, this procedure allows the patient to preserve her uterus by a minimally invasive procedure.
* Type II submucous myomas, which are often very difficult to completely and safely remove hysteroscopically, are often treated through an open or laparoscopic procedure. Hysteroscopic procedure does not involve intraperitoneal intervention and is therefore expected to be associated with less intra-operative and post-operative complications.
* Fast recovery: after hysteroscopic cryomyolysis only minimal self resolving discomfort is expected and the patient should be able to return to her normal activity within 24-48 hours.
* Hysteroscopic cryomyolysis could broaden the number of providers able to offer patients a hysteroscopic treatment option.

Contacts

Public
Galil Medical

Tavor Building, POB 224
20692 Yokeam
Israel
Scientific
Galil Medical

Tavor Building, POB 224
20692 Yokeam
Israel

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Primary complaint is excessive bleeding
* Subject is able to understand and give informed consent for participation in the study
* Pre-menopausal woman between the ages of 30 and 50 (inclusive)
* Has completed childbearing and not contemplating future fertility
* Has symptomatic uterine fibroids
o Symptomatic subjects defined as
* Abnormal uterine bleeding
* Either menorrhagia or metrorrhagia, or menometrorrhagia (with no infectious or pre-malignant/malignant cause of bleeding)
* Socially disruptive bleeding
* Bleeding defined as bothersome to the patient that interferes with daily activities
* Fibroids type, size, location and number
o 1 submucosal fibroid
o Type I and Type II fibroids
o 2 to 4cm
* Using contraception to prevent pregnancy

Exclusion criteria

* Any evidence of known or suspected infection or pre-malignancy/malignancy
* Desire for future child bearing
* Use of GnRH analogues within 3 months prior to cryotherapy treatment
* Fibroids
o Size > 4 cm
o 2 or more submucosal fibroids
o Fibroid distance from serosa is less than 1 cm

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-07-2008
Enrollment:	3
Type:	Actual

Ethics review

Approved WMO

Date:	22-04-2008
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL20928.029.07