Incidence and predictors of re-intervention after Novasure endometrial ablation: a validation study in patients with abnormal uterine bleeding with data extraction from the Electronic Health Record and a Clinical Data Collector.

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20077

Source
NTR

Brief title
SEED

Health condition

Abnormal Uterine Bleeding

Sponsors and support

Primary sponsor: Máxima MC
Source(s) of monetary or material Support: Máxima MC

Intervention

Outcome measures

Primary outcome

Surgical re-intervention in Máxima MC in women with abnormal uterine bleeding who underwent Novasure treatment in 2018

Secondary outcome

- Patient characteristics: age, BMI, height and weight
- Time between Novasure and re-intervention
- Pre-existent Tubal ligation
- Pre-existent dysmenorrhea
- Uterine position
- Time and power ablation
- Analgesia (sedation, treatment room, Operating Room)

Study description

Background summary

Endometrial ablation using Novasure is a treatment in which the endometrium is removed in women with abnormal uterine bleeding. Unfortunately, in 10-20% of women, surgical re-intervention in the form of another ablation or even a hysterectomy is required because initial treatment has failed. For this reason, it is important to identify prognostic risk factors which are associated with treatment failure, and to continuously and conveniently evaluate clinical data in order to improve the effectiveness of Novasure endometrial ablation.

The current standard for real-world data extraction from the Electronic Health Record (EHR) is manual search and review of free text in EHR. This is an inefficient, time-consuming and laborious process, which is difficult to monitor and reproduce and, moreover, it contravenes the General Data Protection Regulation (GDPR). Clinical Data Collector (CDC) is a text mining software tool to collect structured and unstructured data from the EHR in a pseudonymised way through a search query. The search can be saved and reused, which increases verifiability. Data extraction with CDC has the additional advantage that only data that is relevant for the search query (minimizing data extraction) is automatically requested and pseudonymised (i.e. GDPR security). With the use of CDC, the efficiency of data extraction can be greatly improved. However, the validity of the extracted data depends on the quality of the CDC search. This search must take into account the different ways of registering in EHR by care professionals. Preparing a good search query in CDC can therefore be a challenge and must be critically evaluated.

In this study, we want to evaluate whether EHR data extraction with CDC to study the effectiveness of Novasure endometrial ablation is reliable compared to manual EHR data

extraction.

Study objective

Data extraction with CDC to study the effectiveness of Novasure endometrial ablation is reliable compared to manual EHR data extraction

Study design

Primary outcome:
- Surgical reintervention measured during a follow-up of 2 years after Novasure endometrial ablation as recorded in the EHR by the healthcare professional.

Secondary outcomes as recorded in the EHR by the healthcare professional:
- Patient characteristics measured at the time of Novasure endometrial ablation. If not possible/available: measurement at a time point as close as possible to the intervention
- Time between Novasure endometrial ablation and re-intervention
- Pre-existent Tubal ligation (i.e. any time point before Novasure endometrial ablation)
- Pre-existent dysmenorrhea (i.e. any time point before Novasure endometrial ablation)
- Uterine position, preferably the last measurement before Novasure endometrial ablation
- Time and power ablation at the time of Novasure endometrial ablation
- Analgesia (sedation, treatment room, Operating Room) at the time of Novasure endometrial ablation

Intervention

Novasure endometrial ablation

Contacts

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Eligibility criteria

Inclusion criteria

Woman who suffer from abnormal uterine bleeding and who previously underwent Novasure treatment in 2018 in Máxima MC

Exclusion criteria

Previous surgical intervention for heavy menstrual bleeding

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-01-2021
Enrollment:	120
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type: Not applicable

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
NTR-new	NL9268
Other	Commissie Lokale Uitvoerbaarheid Máxima Medical Center : L20.188

Study results