Sonalleve MR-HIFU with Direct Skin Cooling: Proof of Concept Study

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The primary objective of this study is to evaluate feasibility of performing MR-HIFU treatment of uterine fibroids in a Philips Sonalleve MR-HIFU system equipped with a Direct Skin Cooling device. Secondary objective is evaluation of safety.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive neoplasms female benign
Study type	Observational non invasive

Summary

ID

NL-OMON38872

Source
ToetsingOnline

Brief title
Sonalleve DISC Proof of Concept

Condition

- Reproductive neoplasms female benign
- Uterine, pelvic and broad ligament disorders

Synonym
Myoma, uterine fibroid

Research involving
Human

Sponsors and support

Primary sponsor: Philips Medical Systems, MR Finland
Source(s) of monetary or material Support: Ministerie van OC&W,Philips Medical System;MR Finland

Intervention

Keyword: MR guided focused ultrasound, Non-invasive therapy, Skin cooling device, Uterine fibroids

Outcome measures

Primary outcome

Feasibility of MR-HIFU treatment with Sonalleve with Direct Skin Cooling will be measured by recording whether treatments are completed successfully using the investigational device. Treatment completion will be judged by the treating physician and recorded in the Case Report Form (CRF).

The rate of successful treatment completion will be determined. An individual treatment is deemed successful if the treating physician is able to complete the treatment as planned using the MR-HIFU device with Direct Skin Cooling. If a treatment needs to be aborted before the desired ablation volume is achieved, as judged by the treating physician, it will be counted as a failure. If the backup CE-labeled Sonalleve device without Direct Skin Cooling needs to be used to complete the treatment, it will be counted as a failure.

Secondary outcome

The following measurements will be performed to gain additional insight into safety and feasibility of the treatment with the Philips Sonalleve MR-HIFU device with Direct Skin Cooling:

1. Safety Endpoint:

Incidence of adverse events and Serious Adverse Events will be recorded in the

CRF, and their relatedness to the investigational device and the study in general will be assessed.

2. Physician Acceptance:

Acceptance of the device by the treating physician will be evaluated by determination of the Net Promoter Score. After each treatment, the treating physician will be asked the question *How likely is it that you would recommend this device to your colleagues?* Answers will be recorded as a score from 0 to 10, with 0 being the least likely and 10 being the most likely. The result will be recorded in the CRF.

Study description

Background summary

During MR-HIFU treatments, undesired warming outside of the targeted area may occur due to the deposition of thermal energy. In standard MR-HIFU therapy, the effects of this undesired warming are mitigated e.g. by enforcement of cooling periods between ultrasound applications. Introduction of a cooled interface which allows direct cooling of the patients* skin can further mitigate undesired warming, potentially increasing treatment efficiency and providing an additional safety buffer. This feasibility trial is designed to demonstrate the concept for a Direct Skin Cooling device added to the Philips Sonalleve MR-HIFU device for uterine fibroid treatments.

Study objective

The primary objective of this study is to evaluate feasibility of performing MR-HIFU treatment of uterine fibroids in a Philips Sonalleve MR-HIFU system equipped with a Direct Skin Cooling device. Secondary objective is evaluation of safety.

Study design

Prospective, non-randomized feasibility study (Proof of Concept).

Study burden and risks

Risk assessment has concluded that the overall risk level does not differ from the CE-marked Sonalleve system. One additional risk mechanism potentially leading to an adverse event was identified as specifically related to the cooling device. The adverse event associated with this mechanism is a non-freezing cold injury to the patients* skin, due to prolonged exposure to the cooled surface. Due to the temperature and exposure time limitations in this protocol, the probability of occurrence for this specific event is considered remote.
In case the treatment cannot be successfully completed using the device with Direct Skin Cooling, treatment with a normal, CE-marked Sonalleve device will be available to the patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patient selected for MR-HIFU treatment of Uterine Fibroids or Adenomyosis.
Age >= 18 years.
Patient capable of giving informed consent in writing and able to attend study visits.

Exclusion criteria

Discretion of the principal investigator, e.g. in presence of clinically relevant medical history or abnormal physical findings that could interfere with the safety of the participant.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-11-2013
Enrollment:	8
Type:	Actual

Medical products/devices used

Generic name:	Direct Skin Cooling Device
Registration:	No

Ethics review

Approved WMO

Date:	17-10-2013

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL45458.041.13