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High intensity focused ultrasound for the treatment of fibroadenoma

Submission date
23/01/2014

Recruitment status
No longer recruiting

Registration date
04/02/2014

Overall study status
Completed

Last Edited
09/08/2019

Condition category
Cancer

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Fibroadenoma is a common benign lump of the breast present in 1 in 10 women attending breast clinics. The current management of these lumps is patient reassurance once diagnosed and surgical removal only if the lump is growing or is painful. This is because of the risk of undesirable scarring. The aim of this study is to use a high intensity focused ultrasound (HIFU) machine (Echopulse TM) to heat up the breast lump and cause it to shrink. This will eliminate the need for any invasive procedure like surgery and potential undesirable side effects.

Who can participate?
HIFU group: Women over 18 years of age with ultrasound confirmed and symptomatic cases of fibroadenomas. Patients over the age of 25 need a biopsy to confirm the diagnosis of a FAD.
Control group: Patients who are eligible to participate in the study and invited to come back six months after their FAD diagnosis for an additional ultrasound scan in order to determine the natural change in volume of FAD. These patients do not undergo HIFU treatment.

What does the study involve?
HIFU group: All patients are given local anaesthetic and treated with the ultrasound device as a day case in the outpatient unit. The ultrasound machine is used to image the lump and determine where to treat. Once in the suite patients are placed on their side and local anaesthetic is administered. A gel pad attached to the device is then lowered onto the site of treatment. The HIFU system is used to image the fibroadenomata and set to deliver HIFU treatment. The total treatment time is about 90 minutes. Once the treatment is completed the patient is observed in the discharge suite for 1 hour before being discharged when they meet the local discharge criteria. All patients are reviewed after the procedure and at 2 weeks, 3, 6 and 12 months with a repeat ultrasound scan at each appointment.
Control group: all patients are asked to return to the breast clinic six months after initial diagnosis of their FAD for an additional ultrasound scan.

What are the possible benefits and risks of participating?
HIFU group: The benefit for the patients is that they will not have invasive surgery to treat their fibroadenoma and this will prevent any potential scarring or cosmetic complications. Participants will experience some discomfort after the procedure requiring oral pain relief. The

HIFU treatment can result in skin changes and we would expect patients to experience a degree of mild swelling and redness with or without bruising at the treatment site (lasting up to 14 days). Rarely patients may experience minimal changes in skin colour (lasting several months) and superficial skin burns (resolving without any further medical treatment).
Control group: No additional benefits or risks.

Where is the study run from?
Guy's NHS Foundation Hospital (UK)

When is the study starting and how long is it expected to run for?
January 2014 to October 2016

Who is funding the study?
Unrestricted educational grant from Theraclion (France)

Who is the main contact?
Mr Muneer Ahmed
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT02139683

Secondary identifying numbers
Version 3.0 (05/11/2014) Ref: 13/LO/1221

Study information

Scientific Title
High Intensity Focused Ultrasound for the treatment of Fibroadenoma (HIFU-F) Study: a non-randomised study

Acronym
HIFU-F

Study objectives
This non-invasive procedure using high intensity focused ultrasound can potentially replace the need for surgical interventional and minimise the risk of scarring and undesirable cosmetic outcomes. In addition to minimising in-patient care requirements.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London-Bromley, 27/08/2013, ref.: 13/LO/1221

Study design
Non-randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Not available in web format, please use the contact details above to request a patient information sheet

Health condition(s) or problem(s) studied
Fibroadenoma

Interventions
Current interventions as of 02/06/2016:
HIFU group
Patients with confirmed fibroadenomas will be administered a local anaesthetic and a coupling media in the form of a gel pad attached to the device will then be lowered onto the site of treatment. The Echopulse TM will be used to image the lesion in 2 perpendicular dimensions and set to deliver HIFU to the circumferential surface area of the lesion. Once the treatment is completed the patient will be observed in the discharge suite for a period of 1 hour prior to discharge subject to satisfactorily complying with local day case discharge protocols. All patients will be reviewed after the procedure and at 2 weeks, 3, 6 and 12 months with a repeat ultrasound scan at each appointment.

Control group
Patients will undergo an ultrasound scan six months after FAD diagnosis in order to determine the change in volume over time.

Previous interventions:
Patients with confirmed fibroadenomas will be administered a local anaesthetic and a coupling media in the form of a gel pad attached to the device will then be lowered onto the site of treatment. The Echopulse TM will be used to image the lesion in 2 perpendicular dimensions and set to deliver HIFU to the circumferential surface area of the lesion. Once the treatment is completed the patient will be observed in the discharge suite for a period of 1 hour prior to discharge subject to satisfactorily complying with local day case discharge protocols.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Current primary outcome measures as of 02/06/2016:
1. Changes in volume of fibroadenomata as recorded on ultrasound imaging
2. Change in volume in comparison to a control group
All outcome measures are measured prior to treatment, straight after treatment, and at 2 weeks, 3, 6 and 12 months follow-up.

Previous primary outcome measures:
Fibroadenoma size reduction post-treatment on ultrasound imaging

Secondary outcome measures
Added 02/06/2016:
1. Complications
2. Patient recorded outcome measures (pain symptoms)
3. Mean treatment time

4. Cost-effectiveness
All outcome measures are measured prior to treatment, straight after treatment, and at 2 weeks, 3, 6 and 12 months follow-up.

Overall study start date
01/01/2014

Completion date
01/10/2016

Eligibility

Key inclusion criteria
1. Patients over 18 years of age
2. Fibroadenomata diagnosed according to local hospital protocol; ultrasound alone on patients <25 and ultrasound plus core-biopsy in patients >25 (Graded B2 or less)
3. Visible on ultrasound (Graded U2/U3)
4. Definitive diagnosis of fibroadenomata confirmed by the breast multi-disciplinary team meeting (MDT)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
50+50 controls

Key exclusion criteria
1. Lesion with atypia or suspicion of phyllodes (Graded B3 or greater)
2. Pregnant or lactating women
3. History of laser or radiation therapy to the targeted breast

Date of first enrolment
28/01/2014

Date of final enrolment
01/10/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
King's College London, Guy's & St Thomas' Hospitals
London
United Kingdom
SE1 9RT

Sponsor information

Organisation
King's College London and Guy's and St Thomas' Hospitals NHS Foundation Trust (UK)

Sponsor details
R&D Department
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Industry

Funder Name
Theraclion (France)

Results and Publications

Publication and dissemination plan

The results will be submitted for publication but no timeframe has been set for this.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	14/04/2015		Yes	No
Results article	results	01/12/2016		Yes	No
Results article	results	01/11/2018		Yes	No
HRA research summary			28/06/2023	No	No