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The ENTREPPMENT trial: comparing treatments for inguinal hernia

Submission date
09/01/2012

Recruitment status
No longer recruiting

Registration date
08/02/2012

Overall study status
Completed

Last Edited
04/08/2021

Condition category
Digestive System

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

Plain English summary of protocol

Background and study aims
Hernia (a lump that results from a part of the bowel slipping through a weakness in the abdominal wall) of the groin is a common disease; every year 30,000 hernia repairs are performed in the Netherlands. The main serious adverse event is postoperative chronic pain, not recurrence. A recently completed study showed less postoperative chronic pain after transinguinal hernia repair (TIPP) when compared to Lichtenstein, the reference technique used in the Netherlands.
A new technique transrectus sheath preperitoneal (TREPP) has been developed that is expected to reduce postoperative chronic pain even more. This study will compare both techniques.

Who can participate?
Adults with an American Society of Anesthesiologists (ASA) classification < 4 (not too much comorbidity), with an unilateral hernia of the groin that has never been repaired before.

What does the study involve?
TIPP and TREPP will be compared. When a patient is eligible they will be randomly assigned to receive either a repair by TIPP or by TREPP. They are both open repair techniques.

What are the possible benefits and risks of participating?
There are no benefits.
There are no risks, other than the risk of having surgery.

Where is the study run from?
The study will be performed in five medical centers in the Netherlands (Radboud University Nijmegen Medical Center; Gelderse Vellei Hospital Ede; St Jansdal Hospital Harderwijk; St. Elisabeth Hospital and TweeSteden Hospital Tilburg/Waalwijk).
The lead center is Radboud University Nijmegen Medical Center.

When is the study starting and how long is it expected to run for?
The trial will start mid of 2012, expected time for inclusion is 1-1.5 years. Total follow up is 1 year.

Who is funding the study?
Radboud University Nijmegen Medical Center

Who is the main contact?
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Study website
http://www.entreppment.nl

Contact information

Type(s)
Scientific

Contact name
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6525 GA

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The ENTREPPMENT trial: the TransREctus sheath Preperitoneal mesh repair Procedure (TREPP) compared to the TransInguinal Preperitoneal Procedure (TIPP): a randomised clinical trial

Study objectives
TREPP will reduce postoperative chronic pain after inguinal hernia repair with 50%, compared to TIPP.

On 21/02/2014 the following changes were made to the trial record:
1. The anticipated start date was changed from 01/06/2012 to 20/02/2014
2. The anticipated end date was changed from 01/06/2014 to 20/08/2016

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval obtained from CMO region Arnhem-Nijmegen on 24/07/2012, ref 2012/060, local ref NL38842.091.12.

Study design
Interventional multi-center randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Inguinal hernia

Interventions
800 patients will be randomised into the two operation techniques compared:
1. TREPP (transrectus sheath preperitoneal mesh repair) (400 participants)
2. TIPP (transinguinal preperitoneal repair) (400 participants)

Both hernia repairs are performed in day treatment, or with a total stay of 1 night in hospital. Both groups will visit the outpatient department at 6 weeks, 6 months and 12 months.

A physical exam will be done for evaluation of numbness of the operation area; questionnnaires are filled in (SF-36, EuroQol 3D, pain disability index). Total follow up is 1 year.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Severe adverse events, e.g. postoperative chronic pain, mortality, recurrence, bleeding

Secondary outcome measures

1. Hospital stay
2. Operation time
3. Return to daily activities (e.g. work)
4. Health status
5. Economic evaluation (cost effectiveness)

Overall study start date
20/02/2014

Completion date
31/03/2018

Eligibility

Key inclusion criteria
1. Primary, unilateral groin hernia
2. Aged 18-80 years
3. American Society of Anaesthesiologists (ASA) Classification 1-3
4. Signed informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
800

Key exclusion criteria
1. Recurrent hernia
2. Scrotal/femoral hernia
3. Acute incarcerated inguinal hernia
4. Psychiatric disease or other reasons making follow-up or questionnaires unreliable
5. Previous preperitoneal surgery (e.g. radical prostatectomy)

Date of first enrolment
20/02/2014

Date of final enrolment
20/08/2016

Locations

Countries of recruitment
Netherlands

Study participating centre
Radboud University Nijmegen Medical Center
Nijmegen
Netherlands
6525 GA

Sponsor information

Organisation
Radboud University Nijmegen Medical Center (Netherlands)

Sponsor details
Geert Grooteplein-Zuid 10
Nijmegen
Netherlands
6525 GA

Sponsor type
Hospital/treatment centre

Website
http://www.umcn.nl/

ROR
https://ror.org/05wg1m734

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Radboud University Nijmegen Medical Center (Netherlands)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/03/2019

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	03/03/2013		Yes	No
Abstract results	Abstract provisionally accepted for ESA congress May 2021 Cologne	02/08/2021	04/08/2021	No	No