

The ENTREPPMENT trial: comparing treatments for inguinal hernia

Submission date 09/01/2012	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 08/02/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 04/08/2021	Condition category Digestive System	<input type="checkbox"/> 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?
Willem Bökkerink
Willem.Bokkerink@radboudumc.nl

Study website
<http://www.entreppment.nl>

Contact information

Type(s)
Scientific

Contact name
Dr Willem Bökkerink

Contact details
Radboud University Nijmegen Medical Center
Geert Grooteplein Zuid 10
Nijmegen
Netherlands
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; questionnaires 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