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Inguinal hernia management: operation or observation? A randomised controlled multicentre trial

Submission date 20/12/2005	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 20/12/2005	**Overall study status** Completed	
Last Edited 18/11/2008	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NTR221

Study information

Scientific Title

Study objectives
Non-inferiority hypothesis: observation is not inferior to operation with respect to the mean of pain and discomfort during 3 years follow-up.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the local medical ethics committee

Study design
Multicentre, randomised, active controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Interventions
1. Operation
2. No intervention, observational management of the inguinal hernia

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The mean of 4 pain/discomfort scores during a follow-up period of 3 years.

Secondary outcome measures
Quality adjusted life years (QALY) with quality weights measured with the EuroQol and in a sensitivity analysis with a transformed 36-item short form (SF-36) utility weight, medical and non-medical costs and event-free survival at 2 years.

Overall study start date
01/01/2006

Completion date
01/01/2011

Eligibility

Key inclusion criteria
1. Unilateral inguinal hernia
2. Males
3. Medial or lateral inguinal hernia
4. Aged greater than or equal to 50 years
5. Description I or II of pain or discomfort interfering with daily activity
6. Primary or recurrent inguinal hernia
7. Informed consent (addendum V)

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
800

Key exclusion criteria
1. Gender: female
2. Bilateral inguinal hernia
3. Femoral hernia
4. Description III or IV of pain or discomfort interfering with daily activity
5. Acute hernia complication (bowel obstruction, incarceration, strangulation, peritonitis or perforation)
6. Patient classified as American Society of Anaesthesiologist Class 4
7. Scrotal hernia (cannot be corrected laparoscopically)
8. Patient is unable to speak Dutch
9. Physical activity: patient travels regularly during which professional medical help is not always accessible
10. Inguinal hernia not apparent during ultrasonography

Date of first enrolment
01/01/2006

Date of final enrolment
01/01/2011

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus Medical Centre
Rotterdam
Netherlands
3015 GD

Sponsor information

Organisation
Erasmus Medical Centre (Netherlands)

Sponsor details
Dr Molewaterplein 40/50
Rotterdam
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3000 CA

Sponsor type
University/education

Website
http://www.erasmusmc.nl/

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration