ISRCTN31866667 https://doi.org/10.1186/ISRCTN31866667

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

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

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Prof J. Jeekel

**Contact details**
Erasmus Medical Centre
Department of General Surgery
Molewaterplein 40
Rotterdam
Netherlands
3015 GD
+31 (0)10 463 3718
j.jeekel@erasmusmc.nl

## 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
Netherlands
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