

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

Submission date 20/12/2005	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 20/12/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 18/11/2008	Condition category Digestive System	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Male

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration