# Hernia Umbilicalis Mesh versus Primary suture

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
20/04/2006		☐ Protocol		
Registration date 17/08/2006	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	[] Individual participant data		
07/01/2021	Digestive System			

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Johan Lange

#### Contact details

Dr. Molewaterplein 40 Rotterdam Netherlands 3015 GD

-

j.lange@erasmusmc.nl

# Additional identifiers

EudraCT/CTIS number

**IRAS** number

ClinicalTrials.gov number

**Secondary identifying numbers** N/A

# Study information

Scientific Title

### Hernia Umbilicalis Mesh versus Primary suture

#### Acronym

**HUMP** 

# **Study objectives**

In the repair of small umbilical hernias, mesh should be used to prevent recurrence.

# Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approved by the Medical Ethics Committee of Erasmus Medical Centre (Medisch Ethische Toetsings Commissie Erasmus M) on 13/04/2005 (reference number: MEC-2005-043).

# Study design

Randomised controlled trial

# Primary study design

Interventional

# Secondary study design

Randomised controlled trial

# Study setting(s)

Hospital

# Study type(s)

Prevention

### Participant information sheet

# Health condition(s) or problem(s) studied

Umbilical hernia

#### **Interventions**

Mesh or primary suture

### Intervention Type

Other

#### Phase

**Not Specified** 

#### Primary outcome measure

Recurrence

### Secondary outcome measures

Quality of life

# Overall study start date

01/05/2006

# Completion date

01/05/2008

# **Eligibility**

# Key inclusion criteria

Patients with a primary umbilical hernia

# Participant type(s)

**Patient** 

#### Age group

Adult

# Sex

Both

# Target number of participants

300

### Total final enrolment

300

### Key exclusion criteria

- 1. Aged under 18 years
- 2. Peritoneal dialysis
- 3. Liver cirrhosis
- 4. Recurrence
- 5. Acute strangulation
- 6. American Society of Anesthesiologists (ASA) score more than III
- 7. Midline laparotomy in history

#### Date of first enrolment

01/05/2006

### Date of final enrolment

01/05/2008

# **Locations**

#### Countries of recruitment

Netherlands

# Study participating centre

# **Dr. Molewaterplein 40**Rotterdam

Netherlands 3015 GD

# Sponsor information

# Organisation

Erasmus Medical Center (The Netherlands)

### Sponsor details

Dr Molewaterplein 40 Rotterdam Netherlands 3015 GD +31 (0) 10 463 9222 j.lange@erasmusmc.nl

### Sponsor type

Hospital/treatment centre

#### **ROR**

https://ror.org/018906e22

# Funder(s)

# Funder type

Hospital/treatment centre

#### **Funder Name**

Erasmus Medical Centre Rotterdam

# **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

# Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	03/03/2018	07/01/2021	Yes	No