

# Sensitivity and predictive value of Functional Cine Magnetic Resonance Imaging (MRI) detecting intra-abdominal adhesions

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The purpose of the study is to define the accuracy of functional cine MRI detecting adhesions to the abdominal wall expressed in sensitivity, specificity, and positive and negative predictive value. In addition MRI findings of organ to organ...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Gastrointestinal conditions NEC
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON39099

### Source

ToetsingOnline

### Brief title

Cine-MRI detecting intra-abdominal adhesions

### Condition

- Gastrointestinal conditions NEC
- Gastrointestinal therapeutic procedures

### Synonym

adhesions; bowel adhesions

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Sint Radboud

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** abdominal surgery, adhesions, cine-MRI, diagnostics

## Outcome measures

### Primary outcome

The abdominal wall is divided in 9 segments for analysis.

Primary objective is Specificity and Sensitivity of functional MRI detecting adhesions to the abdominal wall per segment.

### Secondary outcome

Mapping of organ-to-organ adhesions by functional MRI and subsequent surgery (e.g. bowel-bowel, bowel-bladder).

## Study description

### Background summary

Adhesions are a frequent problem in abdominal surgery. In the majority of patients adhesions form a few days post-operative. The formation of adhesions is part of normal wound healing, comparable to the formation of scar tissue. However, in some patients adhesions cause severe complaints such as chronic pain, obstruction and strangulation of the bowel. Adhesions can also obstruct access to the peritoneal cavity and complicate reoperations. A frequent complication is inadvertent enterotomy at trocar sites in laparoscopy. Adhesiolysis is often necessary during reoperation. Adhesiolysis increases operation time and the risk for complications, such as bleeding and enterotomy. Currently, there are no diagnostic tools to map adhesions accurately. The surgeon only becomes aware of these problems during surgery and has to adjust operation time and procedure accordingly.

### Study objective

The purpose of the study is to define the accuracy of functional cine MRI detecting adhesions to the abdominal wall expressed in sensitivity, specificity, and positive and negative predictive value. In addition MRI findings of organ to organ adhesions are matched to operative findings.

## **Study design**

Prospective multicenter observational trial.

100 Patients fulfilling the in- and exclusion criteria are asked to participate the study. After written informed consent, the patients undergo functional cine MRI. Radiologists are unaware of the morphology of the abdominal scars and type of previous operations. During operation all adhesions are documented in a standard manner. The surgeon is unaware of the results of the cine MRI. Results are delivered independently to the investigators who will take care of analysis.

## **Study burden and risks**

Participation does not effect the standard treatment nor the length of hospital stay. The extra MRI-scan causes no significant risks. The researcher will only collect additional data on illness and medical history.

## **Contacts**

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## **Trial sites**

## Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Males and females 18 years of age and older undergoing a HIPEC-procedure for carcinomatosis peritonei.

Patients willing and capable of providing written informed consent prior to study enrollment

Patients who have had a previous laparotomy or therapeutic laparoscopy (laparoscopic adnex and/or colonic resection).

### Exclusion criteria

Contra- indication for MRI (e.g. severe claustrophobia)

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 01-07-2009

Enrollment: 100

Type: Actual

## Ethics review

Approved WMO

Date: 04-11-2008

Application type: First submission

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date: 05-12-2013

Application type: Amendment

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register	ID
CCMO	NL21364.091.08