

Congenital malrotation in adults

Submission date 02/11/2015	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 25/02/2016	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 02/04/2020	Condition category Digestive System	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Congenital intestinal malrotation, or congenital bowel malrotation, is a condition in which the intestines are twisted. It usually happens when the intestine fails to coil into the correct position in a developing foetus (at around the tenth week of development). In most cases, malrotation is detected within the first month of life however in some people it is not diagnosed until adulthood. When it is diagnosed, the only appropriate treatment option is corrective surgery. During this surgery, the intestine is untwisted and placed into its correct position, or segments are removed if they are damaged and unable to work properly. As the condition usually discovered in childhood, when an adult is suffering from abdominal pain congenital intestinal malrotation is not usually suspected. This means that in many cases it is only discovered in if it is spotted on a scan looking for something else (incidental finding). The aim of this study is to find out how many cases of abdominal pain in adults is due to congenital intestinal malrotation. The study will also look at whether having corrective surgery when malrotation is detected has an effect of their abdominal pain in the long-run.

Who can participate?

Patients over 16 years of age who have intestinal malrotation and are suffering from abdominal pain.

What does the study involve?

Patients who have agreed to take part in the study have a CT scan of their abdomen in order to assess how severe the malrotation is. The patients are then split into three groups based on their age in order to find out if there is a link between the degree of malrotation and their age. The patients then undergo their corrective surgery as planned. During 2012 and 2013, patients who have had corrective surgery between 1 and 12 years previously are contacted by telephone in order to find out if their condition has improved. The patients are asked whether they have experienced pain, nausea, vomiting or constipation, since their surgery.

What are the possible benefits and risks of participating?

There are no direct benefits or risks to patients taking part in this study.

Where is the study run from?

Karolinska Institute (Sweden)

When is the study starting and how long is it expected to run for?
December 2002 to December 2018

Who is funding the study?

1. Swedish Research Council (Sweden)
2. The Foundation Frimurare Barnhuset Stockholm (Sweden)
3. Stockholm City Council (Sweden)
4. Swedish Society for Medical Research (Sweden)
5. Karolinska Institute (Sweden)

Who is the main contact?

Dr Karin Strigård

Contact information

Type(s)

Public

Contact name

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Additional identifiers

Protocol serial number

2012/957-31/3

Study information

Scientific Title

Congenital intestinal malrotation in adolescent and adult patients – a 12-year clinical and radiological survey

Study objectives

Symptomatic malrotation may be a cause of abdominal pain in adults.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Regional Ethical Review Board Stockholm (Etikprövningsnämnden Stockholm), 20/06/2012, ref: 2012/957-31/3

Primary study design

Observational

Study design

Single-centre longitudinal study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Congenital intestinal malrotation

Interventions

All medical records are evaluated with regards to symptoms, surgical procedures, previous disorders and outcomes. For analysis of differences according to age, the patients were divided into three groups (15-20 years, 21-50 years, 51- 67 years). Symptomatic malrotation is then treated by corrective surgery, and routinely assessed six weeks, six months and 12 months after surgery.

During 2012-2013 (1 to 12 years after surgery) a research nurse performed telephone interviews with a semi-structured concept concerning the patients' past and present situation and possible remaining symptoms after surgery. The questions focused on remaining intense or chronic pain, postprandial nausea, vomiting and constipation. Patients were also asked whether they regarded their general physical condition as improved to a high degree, improved with some reservation or without any notable improvement.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Symptom resolution following surgery is determined using semi-structured telephone interviews with a research nurse, during 2012-2013 (1 to 12 years after surgery).

Key secondary outcome(s)

Degree of malrotation is determined using CT scanning at baseline.

Completion date

31/12/2018

Eligibility**Key inclusion criteria**

1. Aged 16 years or over
2. Abdominal pain
3. Malrotation on CT scan

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

Total final enrolment

39

Key exclusion criteria

1. Not understanding oral or written information
2. Under 15 years of age

Date of first enrolment

12/02/2002

Date of final enrolment

10/11/2013

Locations**Countries of recruitment**

Sweden

Study participating centre

Karolinska University Hospital

Hälsovägen 1 - 3

Stockholm

Sweden

141 86

Sponsor information**Organisation**

Karolinska Institutet

ROR

<https://ror.org/04hmgwg30>

Funder(s)

Funder type

Research council

Funder Name

Swedish Research Council (Vetenskapsrådet)

Alternative Name(s)

Swedish Research Council, VR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Sweden

Funder Name

The Foundation Frimurare Barnhuset Stockholm (Stiftelsen Frimurare Barnhuset i Stockholm)

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Sweden

Funder Name

Stockholm City Council (Kommunfullmäktige, Stockholms Stad)

Funder Name

Swedish Society for Medical Research (Svenska Sällskapet för Medicinsk Forskning)

Alternative Name(s)

Swedish Society for Medical Research, SSMF

Funding Body Type

Private sector organisation

Funding Body Subtype

Associations and societies (private and public)

Location

Sweden

Funder Name

Karolinska Institute (Karoklinska Institutet)

Alternative Name(s)

Karolinska Institute, KI

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Sweden

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2016	02/04/2020	Yes	No