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Congenital malrotation in adults

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

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Single-cenre longitudinal study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure

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

Secondary outcome measures
Degree of malrotation is determined using CT scanning at baseline.

Overall study start date
12/02/2002

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

Age group
Mixed

Sex
Both

Target number of participants
39

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

Sponsor details
Solnavägen 1
171 77 Solna
Sweden
Stockholm
Sweden
17177

Sponsor type
University/education

Website
http://ki.se/en/about/startpage

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

Publication and dissemination plan
Publication in two manuscripts detailing study reults and 5 year follow-up.

Intention to publish date
30/06/2019

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