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The CHildrens INterval Appendicectomy (CHINA) Study

Submission date
29/07/2011

Recruitment status
No longer recruiting

Registration date
29/07/2011

Overall study status
Completed

Last Edited
18/04/2017

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
A proportion of children with acute appendicitis develop a swelling around the appendix called an appendix mass. From experience, we know that removing the appendix in such children is likely to result in complications so these children are usually treated with intravenous antibiotics rather than with an operation to remove the appendix. Once the child has recovered, most surgeons recommend an operation (called interval appendicectomy) to remove the appendix several months later to prevent the child from getting appendicitis again. It is not known whether this operation is actually necessary.
Recently there have been a number of studies performed in children and adults suggesting that interval appendicectomy may not be necessary as very few people actually get appendicitis again. Furthermore, there is a risk of complications, a need for hospital admission and a cost implication associated with interval appendicectomy.

Who can participate?
Children aged between 3 and 16 with a diagnosis of acute appendicitis with appendix mass.

What does the study involve?
We plan to determine whether interval appendicectomy is necessary by randomly assigning children to one of two groups. One group of children will have an interval appendicectomy and the other group will not. Both groups of children will be followed up regularly for at least a year. Any children who do get appendicitis again will be treated appropriately.

What are the possible benefits and risks of participating?
We aim to generate accurate, reliable data which will allow doctors and parents in the future to make an informed decision about their childrens care. If we are right, we may save four out of every five children with this condition from having an operation that they do not need.

Where is the study run from?
Southampton University Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?
June 2011 to June 2014

Who is funding the study?
BUPA Foundation (UK).

Who is the main contact?
Mr Nigel Hall

Study website
http://www.chinastudy.org.uk

Contact information

Type(s)
Scientific

Contact name
Mr Nigel Hall

Contact details
Southampton University Hospitals NHS Trust
Tremona Road
Southampton
United Kingdom
SO16 6YD

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
10406

Study information

Scientific Title
A prospective randomised evaluation of interval appendicectomy versus conservative follow-up following successful non-operative treatment of appendix mass in children

Acronym
CHINA

Study objectives
A proportion of children who have acute appendicitis develop a swelling around the appendix called an appendix mass. From experience, we know that removing the appendix straight away in such children is likely to result in complications and therefore these children are usually treated with intravenous antibiotics rather than with an operation to remove the appendix.

Once the child has recovered, most surgeons recommend an operation (called an interval appendicectomy) to remove the appendix several months later in order to prevent the child from getting appendicitis again. However, it is not known whether this operation is actually necessary. Recently there have been a number of studies performed in adults that suggest that interval appendicectomy is not necessary as very few people actually get appendicitis again. Additionally, there is a risk of complications, a need for hospital admission and a cost implication associated with interval appendicectomy.

We plan to determine whether interval appendicectomy is necessary in children by randomly assigning children to 1 of 2 groups. One group of children will have an interval appendicectomy and the other group will not. Both groups of children will be followed up regularly for at least a year. Any children who do get appendicitis again will be treated appropriately. We aim to generate accurate, reliable data which will allow doctors and parents of these children to make an informed decision about their care in the future. If we are right, we may save 80-90% of children with this condition from having an operation that they do not need.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Isle of Wight, Portsmouth and South East Hampshire Research Ethics Committee, ref: 10/H05014/67

Study design
Randomised, interventional, prevention, treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Appendicitis in paediatrics

Interventions
1. Interval appendicectomy
2. Planned interval appendicectomy 6-8 weeks following successful non-operative treatment of appendix mass
3. Watchful waiting

4. Regular (3 monthly) observation for a 1 year period
5. Follow Up Length: 12 month(s)
6. Single randomisation only

Intervention Type
Procedure/Surgery

Primary outcome measure
Recurrence of acute appendicitis within 12 months of recruitment

Secondary outcome measures
1. Cost analysis
2. Histology of resected appendix
3. Significant complications during or following interval appendicectomy within 12 months

Overall study start date
01/03/2010

Completion date
01/10/2016

Eligibility

Key inclusion criteria
1. Diagnosis of acute appendicitis with appendix mass
2. Appendix mass palpable clinically, during examination under anaesthetic or identified radiologically (ultrasound or CT scan)
3. Have been successfully treated nonoperatively during the acute stage of the illness
4. Aged >3yrs and <16 yrs
5. Male or female

Participant type(s)
Patient

Age group
Child

Lower age limit
3 Years

Upper age limit
16 Years

Sex
Both

Target number of participants
UK Sample Size: 100

Key exclusion criteria

1. Aged less than 3 years or more than 16 years at the time of initial presentation
2. Co-existing gastrointestinal disease e.g. inflammatory bowel disease
3. Presence of major associated abnormalities or immune defect
4. Inability to obtain informed consent

Date of first enrolment
08/08/2011

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Southampton University Hospitals NHS Trust
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation
Southampton University Hospitals NHS Trust (UK)

Sponsor details
Tremona Road
Southampton
England
United Kingdom
SO16 6YD

Sponsor type
Hospital/treatment centre

Website
http://www.suht.nhs.uk/home.aspx

ROR
https://ror.org/0485axj58

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
BUPA Foundation

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date
31/03/2017

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V3	26/04/2011	15/12/2016	No	Yes
Results article	results	01/04/2017		Yes	No