

# The Childrens INterval Appendicectomy (CHINA) Study

<b>Submission date</b> 29/07/2011	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 29/07/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 18/04/2017	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> 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?
<a href="#">Participant information sheet</a>	version V3	26/04/2011	15/12/2016	No	Yes
<a href="#">Results article</a>	results	01/04/2017		Yes	No