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Long-term outcomes in children born with abdominal wall defects V1

Submission date	Recruitment status	[X] Prospectively registered
25/02/2015	No longer recruiting	☐ Protocol
		☐ Statistical analysis plan
Registration date	**Overall study status**	☐ Results
25/02/2015	Completed	☐ Individual participant data
Last Edited	**Condition category**	☐ Record updated in last year
04/08/2017	Surgery	

Plain English summary of protocol

Background and study aims
Gastroschisis and exomphalos are birth defects in which the wall of the abdomen fails to close properly. Although we have good information about these babies when they are born, there is very little research which investigates the health of babies born with these conditions over the longer-term, i.e. as they are children growing up. In particular, we don't know how the severity of their condition when they are born, and how the different types of surgery used to close the abdominal wall affect children's long-term health and quality of life. This research project into children born with abdominal wall defects aims to find out ways to improve treatment and provide better information about the conditions for families by finding out about their health when they are 7-9 years old.

Who can participate?
Surviving children with gastroschisis born in the UK between October 2006 and March 2008. Children with exomphalos born in the UK between March 2014 and February 2015 who survives to one month of age or is discharged from hospital.

What does the study involve?
Parents of children with gastroschisis aged 7-9 are sent two questionnaires, one for them and one for their child to fill in. These contain questions about their child's health and wellbeing. There are questions about symptoms they may or may not be having and about whether they have been to the doctors or to hospital recently. There are also some general questions about how they feel in themselves, questions about how their tummy looks and how they and their parents feel about it. There are also questions on the impact that having a child with gastroschisis has had on the family.
Parents are also asked whether we can contact their child's teacher to ask some questions about how their child gets on at school. If parents do not wish their child's teacher to be contacted, the information they provide through returning the questionnaires is still included in the study.
Parents of children with exomphalos born between March 2014 and September 2015 are contacted and asked to provide their contact details in order to take part in future questionnaire studies when their children are older.

What are the possible benefits and risks of participating?
The study will not be of direct benefit to participating parents or their children, as the information will be used to improve treatment in the future. It will not change the treatment they currently receive. The questions in the questionnaires are very general and many have been used in other studies involving children, but some parents may find some of them sensitive or upsetting. It is absolutely fine to only answer some, but not all of the questions. Parents will have the direct contact details of the research team and if they are upset or distressed by anything they are asked they will be able to talk to someone from the research team.

Where is the study run from?
29 NHS hospitals in the UK

When is the study starting and how long is it expected to run for?
April 2015 to August 2016

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Mrs Melanie O’Connor

Contact information

Type(s)
Public

Contact name
Mrs Melanie O'Connor

Contact details
University of Oxford
National Perinatal Epidemiology Unit
Old Road
Headington
Oxford
United Kingdom
OX3 7LF

Type(s)
Scientific

Contact name
Prof Marian Knight

ORCID ID
http://orcid.org/0000-0002-1984-4575

Contact details
University of Oxford
National Perinatal Epidemiology Unit
Old Road

Headington
Oxford
United Kingdom
OX3 7LF

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
17762

Study information

Scientific Title
AIMES: assessing the long-term impact of early surgical care in children born with abdominal wall defects

Study objectives
This project will investigate children born with abdominal wall defects assessing both school and patient/ parent-reported outcomes. Teachers, parents and children will be asked to complete a questionnaire about their/the child's general health and well-being. The data generated from this study will relate outcomes to severity of disease and initial operative management in order to inform evidence-based practice and parental counselling.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London - Camberwell St Giles, 23/12/2014, ref: 14/LO/1949

Study design
Non-randomised; Interventional and Observational; Design type: Treatment, Cohort study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Children; Subtopic: All Diagnoses; Disease: All Diseases

Interventions
The interventions to be investigated all relate to the initial surgical management after birth. The four main groups to be examined will be:
Infants with simple gastroschisis managed initially with operative fascial closure
Infants with simple gastroschisis managed initially with a preformed silo
Infants with simple gastroschisis managed initially with any other closure method
Infants with complex gastroschisis managed initially with any closure method.

Intervention Type
Procedure/Surgery

Primary outcome measure
Health-related quality of life; Timepoint(s): 7 - 9 years of age

Secondary outcome measures
Morbidity; Timepoint(s): 7 - 9 years of age

Overall study start date
20/04/2015

Completion date
31/12/2017

Eligibility

Key inclusion criteria
1. Any surviving infant with gastroschisis born in the UK between October 2006 and March 2008 who completes, or their parent completes, a questionnaire.
2. Any infant with exomphalos born in the UK between March 2014 and February 2015 who survives to one month of age or discharge home whose parent provides their contact details.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 500; UK Sample Size: 500; Description: All recruitment to take place at the University of Oxford with 28 Participant Identification Centres across the UK.

Key exclusion criteria

1. Any infant with gastroschisis born in the UK between October 2006 and March 2008 who has subsequently died.
2. Any infant with exomphalos born in the UK between March 2014 and February 2015 who dies before one month of ageor discharge home.

Date of first enrolment

20/04/2015

Date of final enrolment

31/08/2016

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University of Oxford
National Perinatal Epidemiology Unit
Old Road
Headington
Oxford
United Kingdom
OX3 7LF

Sponsor information

Organisation

University of Oxford

Sponsor details

Wellcome Trust Centre for Human Genetics
Roosevelt Drive
Oxford
England
United Kingdom
OX3 7BN

Sponsor type

Hospital/treatment centre

ROR

https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The findings of this study will be presented at specialist conferences, such as the BAPS Annual Congress in July 2017. Resulting work will also be submitted for publication in peer-reviewed journals, with an anticipated publication date of Autumn 2017. Findings will also be fed back to a parental advisory group and thence, to the relevant patient and parent groups.

Intention to publish date

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?
HRA research summary			28/06/2023	No	No