

# Recognition of pressure build-up in the skull using a three-dimensional eye scanner in children

<b>Submission date</b> 23/12/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 28/01/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 14/06/2022	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Some children have health conditions which place them at risk of having raised pressure in the skull, which can cause vision loss, developmental delay, and even death, if not recognised and treated. One of these conditions is called craniosynostosis, in which a baby's skull may not grow properly. This happens when the joining parts of the baby's skull called 'sutures' close before their head has fully formed. As a result, babies with craniosynostosis usually have an unevenly shaped head. Other conditions that may put children at risk of raised pressure in the skull include brain tumours, hydrocephalus (excess fluid in the brain), and idiopathic intracranial hypertension (raised pressure with no known cause).

Many children at risk of raised pressure in the skull need urgent medical and surgical treatment. It is important that doctors recognise rising pressure in the skull because too much pressure can lead to problems with the brain and vision. However, it is very hard for doctors to measure this.

This study will want to look at a special technique called optical coherence tomography (OCT) to see if this can recognise early changes associated with raised pressure in the skull. OCT is a three-dimensional eye scanning device that looks at the structure of the eye in amazingly minute detail. It is completely safe to use. Up until recently, this technique could not be used on babies and young children because they could not cooperate with the large table-mounted devices for adults. However, the study team are now using a handheld OCT device that is suitable for babies and young children. This device only takes two seconds to scan the eye.

The study team want to use this device to look for early changes in parts of the eye (the optic nerve and the retina). These changes could recognise early changes associated with raised pressure in the skull (called intracranial hypertension).

It is hoped that this study has the potential to improve the care that children receive and to improve clinical outcomes, including quality of vision and quality of life. The study team aims to improve early referral for those babies and young children who need surgery, whilst also protecting other babies and young children from unnecessary surgery if this is not required.

#### Who can participate?

Children aged under 18 years with a diagnosis of craniosynostosis or other conditions associated with the risk of intracranial hypertension.

#### What does the study involve?

This study will involve seeking consent from parents in clinics. The study team will then scan the participant's eyes with handheld OCT to see if there are any changes in the eyes to suggest that there might be rising pressure in the skull. Finally, the OCT results will be compared with the actual pressure measure in the operating theatre and/or other clinical signs of raised pressure in the skull to see how well OCT performs in this role. The study team will also look at vision and other important clinical outcomes.

#### What are the possible benefits and risks of participating?

The benefits for those taking part are the opportunity to have non-invasive OCT examination, which could help the researchers understand the condition better and protect children at risk of raised pressure in the skull. OCT imaging is safe as it simply uses light, therefore this cannot directly cause any risk to the patient. Adverse events will be managed as per standard hospital policy via the GOSH Patient Advice and Liaison Service and Oxford University Hospitals Patient Advice and Liaison Service.

#### Where is the study run from?

Great Ormond Street Hospital for Children NHS Foundation Trust (UK) and John Radcliffe Hospital, Oxford University Hospitals NHS Foundation Trust (UK)

#### When is the study starting and how long is it expected to run for?

From July 2018 to September 2023

#### Who is funding the study?

The National Institute for Health Research (NIHR) (UK)

#### Who is the main contact?

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Dr Sohaib Rufai (scientific), [sohaib.rufai@nhs.net](mailto:sohaib.rufai@nhs.net)

## Contact information

#### Type(s)

Scientific

#### Contact name

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Public

**Contact name**

Mrs Sam Kerr

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## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number**

105137

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

IRAS 105137, UOL0348, EDGE ID 13710

## Study information

**Scientific Title**

Recognition of Intracranial hypertension in children using handheld Optical coherence tomography

**Acronym**

RIO

**Study objectives**

Handheld optical coherence tomography (OCT) can serve as an effective, non-invasive clinical measure to recognise intracranial hypertension (IH) and/or clinical sequelae thereof.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 25/10/2019, East Midlands – Nottingham 2 Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44(0)207 104 8169; nottingham2.rec@hra.nhs.uk), ref: 12/EM0261

**Study design**

Multicentre observational diagnostic accuracy study

**Primary study design**

Observational

**Secondary study design**

Longitudinal study

**Study setting(s)**

Hospital

**Study type(s)**

Diagnostic

**Participant information sheet**

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

**Health condition(s) or problem(s) studied**

Paediatric intracranial hypertension

**Interventions**

Current interventions as of 14/06/2022:

Subjects will be recruited consecutively from the ophthalmology clinic at Great Ormond Street Hospital (GOSH), London, and from the Oxford Craniofacial Unit, Oxford. In addition, subjects will be recruited from the admissions ward prior to 48-hour ICP assessment and/or cranial vault expansion surgery, should this be their first stage of clinical care. In addition, subjects will be recruited from the admissions ward prior to 48-hour ICP assessment and/or cranial vault expansion surgery, should this be their first stage of clinical care when referred to GOSH.

The study team will then scan the eyes with handheld OCT to see if there are any changes in the eyes to suggest that there might be rising pressure in the skull. Finally, the OCT results will be compared with the actual pressure measure in the operating theatre and/or other clinical signs of raised pressure in the skull to see how well OCT performs in this role.

Previous interventions:

Subjects will be recruited consecutively from the ophthalmology clinic at Great Ormond Street Hospital (GOSH), London. In addition, subjects will be recruited from the admissions ward prior to 48-hour ICP assessment and/or cranial vault expansion surgery, should this be their first stage of clinical care when referred to GOSH.

The study team will then scan the eyes with handheld OCT to see if there are any changes in the eyes to suggest that there might be rising pressure in the skull. Finally, the OCT results will be compared with the actual pressure measure in the operating theatre and/or other clinical signs of raised pressure in the skull to see how well OCT performs in this role.

## Intervention Type

### Procedure/Surgery

#### Primary outcome measure

Current primary outcome measures as of 14/06/2022:

1. Optical coherence tomography (OCT) parameters measured using a handheld device (Envisu C2300, Leica Microsystems, Wetzlar, Germany, and Spectralis Flex, Heidelberg Engineering, Heidelberg, Germany) at baseline, follow-up visits (where applicable), and study end. A 12×8-mm scanning window will be used in the acquisition protocol. The 3-dimensional raster scan for both scan sequences will consist of 80 B-scans and 600 A-scans per B-scan line resulting in a short acquisition time (1.9 seconds) enabling imaging of the ONH and fovea with minimal movement artefact
  - 1.1. Cup and disc parameters (cup depth, cup width, disc width, cup to disc ratio)
  - 1.2. Rim parameters (nasal and temporal ppRNFL thickness, rim area, Bruch's membrane opening-minimum rim width (BMO-MRW), Bruch's membrane orientation
  - 1.3. Retinal parameters (macular and perimacular retinal thickness, foveal pit width, foveal pit depth, foveal pit area, segmentation of all retinal layers)
2. Intracranial pressure measured over 48 h intraparenchymally using catheter and bolt system (Neurovent-P, RAUMEDIC AG, Helmbrechts, Germany, and Codman ICP Monitor, Integra Lifesciences, Princeton, NJ, United States) at baseline, follow-up visits (where applicable), and study end

#### Secondary outcome measures

1. Visual acuity measured using logMAR chart vision tests (or preferential looking where logMAR chart vision test not possible) wherever possible at baseline, follow-up visits (where applicable), and study end
2. Visual electrophysiology measured using visual evoked potentials (VEPs) wherever possible at baseline, follow-up visits (where applicable), and study end
3. Peripheral vision measured using visual fields testing wherever possible at baseline, follow-up visits (where applicable), and study end
5. Contrast sensitivity measured using contrast sensitivity testing wherever possible at baseline, follow-up visits (where applicable), and study end
6. OCT parameters measured using a table-mounted device (Spectralis, Heidelberg Engineering, Heidelberg, Germany) at baseline, follow-up visits (where applicable), and study end. The same parameters as per 1.1-1.3 shall be measured.

#### Previous primary outcome measures:

1. Optical coherence tomography (OCT) parameters measured using a handheld device (Envisu C2300, Leica Microsystems, Wetzlar, Germany) at baseline, follow-up visits (where applicable), and study end. A 12×8-mm scanning window will be used in the acquisition protocol. The 3-dimensional raster scan for both scan sequences will consist of 80 B-scans and 600 A-scans per B-scan line resulting in a short acquisition time (1.9 seconds) enabling imaging of the ONH and fovea with minimal movement artefact
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## Overall study start date

01/07/2018

## Completion date

30/09/2023

## Eligibility

### Key inclusion criteria

1. Aged <18 years
2. Clinical and/or genetic diagnosis of craniosynostosis
3. Clinical diagnosis of other conditions associated with the risk of intracranial hypertension, including idiopathic intracranial hypertension, space-occupying lesions, and hydrocephalus

### Participant type(s)

Patient

### Age group

Child

### Upper age limit

18 Years

### Sex

Both

### Target number of participants

39

### Key exclusion criteria

1. Not wishing to participate
2. Incapable of giving consent and without a legal guardian willing or able to do so

### Date of first enrolment

13/02/2020

### Date of final enrolment

30/09/2022

# Locations

## Countries of recruitment

England

United Kingdom

## Study participating centre

**Great Ormond Street Hospital for Children NHS Foundation Trust**

Great Ormond Street

London

United Kingdom

WC1N 3JH

## Study participating centre

**Oxford University Hospitals NHS Foundation Trust**

John Radcliffe Hospital

Headley Way

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OX3 9DU

# Sponsor information

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University of Leicester

## Sponsor details

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## Sponsor type

University/education

## Website

<http://www.le.ac.uk/>

**ROR**

<https://ror.org/04h699437>

## **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**

We will present our findings at relevant meetings and publish in peer-reviewed scientific journals.

**Intention to publish date**

30/09/2024

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

(added 17/12/2021) The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

**IPD sharing plan summary**

Available on request, Published as a supplement to the results publication

**Study outputs**



Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>		11/01/2022	18/01/2022	Yes	No