

Airway Intervention Registry (AIR) extension: Recurrent Respiratory Papillomatosis

Submission date 08/05/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 12/06/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 25/10/2024	Condition category Respiratory	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Recurrent Respiratory Papillomatosis (RRP) causes wart-like growths in the airway which make it difficult to breathe, speak and carry out normal everyday activities. It is a rare condition but is more common and aggressive in children than in adults, affecting 4 in every 100,000 children. There is no known cure for RRP, but symptoms are checked through regular hospital visits, with multiple treatments or procedures under general anaesthetic needed to remove or shrink the growths which can grow back quickly. The problem is that nobody knows which treatments or procedures work best. The aim of this study is to collect information on airway procedures currently being used in UK NHS hospitals to determine which of the treatments are the safest and most effective.

Who can participate?

All patients (adults and children) with RRP receiving at least one treatment in a UK NHS hospital

What does the study involve?

Data is collected on all treatments for RRP in a secure, online database over a 28-month period from 01/04/2018 to 31/08/2020. By determining the most effective treatments for RRP, the aim is to increase the time interval between surgical treatments needed to control symptoms, and reduce the overall number of treatments, the severity and spread of papillomas in the airway, hospital visits, and medications, and ultimately improve quality of life in those with RRP. The safety of the different treatments are assessed to identify those which minimise the spread of disease. From the data collected, patient subgroups are identified who respond better to specific treatments, along with risk factors which contribute to complications (such as tracheostomy).

What are the possible benefits and risks of participating?

The main benefit of participation is the opportunity to address the current lack of evidence around the relative safety and efficacy of the various treatments used to manage RRP, which will improve outcomes for all RRP patients. As this is an observational study, there are no risks of participation, as the clinical treatment a patient receives will be exactly the same regardless of whether they consent to their data being entered to the registry or not.

Where is the study run from?

1. Alder Hey Children's NHS Foundation Trust (UK)
2. Basildon & Thurrock University Hospitals NHS Foundation Trust (UK)
3. Blackpool Teaching Hospitals NHS Foundation Trust (UK)
4. Great Ormond Street Hospital for Children NHS Foundation Trust (UK)
5. North Cumbria University Hospitals NHS Trust (UK)
6. Nottingham University Hospitals NHS Trust (UK)
7. The Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)
8. NHS Greater Glasgow and Clyde (UK)

added 19/11/2019:

9. Abertawe Bro Morgannwg University Health Board (UK)
10. Aintree University Hospital NHS Foundation Trust (UK)
11. Barts Health NHS Trust (UK)
12. Belfast Health and Social Care Trust (UK)
13. Betsi Cadwaladr University Health Board (UK)
14. Birmingham Children's Hospital NHS Foundation Trust (UK)
15. Bradford Teaching Hospitals NHS FT (UK)
16. Cambridge University Hospitals NHS Foundation Trust (UK)
17. Cardiff & Vale University Health Board (UK)
18. City of Sunderland Hospitals NHS Foundation Trust (UK)
19. County Durham and Darlington NHS Foundation Trust (UK)
20. Doncaster And Bassetlaw Hospitals NHS Foundation Trust (UK)
21. East Sussex Healthcare NHS Trust (UK)
22. Frimley Park Hospital NHS Foundation Trust (UK)
23. Hywel Dda Health Board (UK)
24. Imperial College (UK)
25. Isle of Wight NHS Trust (UK)
26. Leeds Teaching Hospitals NHS Trust (UK)
27. Lewisham and Greenwich NHS Trust (UK)
28. London North West Healthcare NHS Trust (UK)
29. Manchester University Hospitals NHS Foundation Trust (UK)
30. NHS Grampian (UK)
31. NHS Lothian (UK)
32. NHS Tayside (UK)
33. Oxford University Hospitals NHS FT (UK)
34. Pennine Acute Hospitals NHS Trust (UK)
35. Salford Royal NHS Foundation Trust (UK)
36. Sheffield Children's NHS Foundation Trust (UK)
37. South Tees Hospitals NHS Foundation Trust (UK)
38. St George's Healthcare NHS Trust (UK)
39. Stockport NHS Foundation Trust (UK)
40. The Shrewsbury and Telford Hospital NHS Trust (UK)
41. University Hospital Birmingham NHS FT (UK)
42. University College London Hospitals NHS Foundation Trust (UK)
43. University Hospital Southampton NHS Foundation Trust (UK)
44. University Hospitals of Derby and Burton NHS Foundation Trust (UK)
45. University Hospitals Plymouth NHS Trust (UK)
46. Wirral University Teaching Hospital NHS FT (UK)

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

September 2017 to August 2022

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

Who is the main contact?
Mrs Kim Fairbairn (née Keltie)
nuth.NMPCE.Air@nhs.net

Contact information

Type(s)
Scientific

Contact name
Mrs Kim Fairbairn (née Keltie)

ORCID ID
<https://orcid.org/0000-0001-5108-6279>

Contact details
Freeman Hospital
Newcastle upon Tyne
United Kingdom
NE7 7DN
+44 (0)191 213 8636
nuth.NMPCE.Air@nhs.net

Additional identifiers

ClinicalTrials.gov (NCT)
NCT03465280

Protocol serial number
38013

Study information

Scientific Title
Airway Intervention Registry (AIR) extension: Recurrent Respiratory Papillomatosis

Acronym
AIR: RRP

Study objectives
Recurrent Respiratory Papillomatosis (RRP) causes wart like growths in the airway which make it difficult to breathe, speak and carry out normal everyday activities. It is a rare condition but is more common and aggressive in children than in adults, affecting 4 in every 100,000 children. There is no known cure for RRP, but symptoms are checked through regular hospital visits, with

multiple therapies or procedures under general anaesthetic needed to remove or shrink the growths which can grow back quickly. The problem is that nobody knows which therapies or procedures work best.

The Airway Intervention Registry (AIR) platform was designed to capture information on airway procedures. It was set up originally to capture information from any patient aged 18 years or less undergoing routine treatment for airway stenosis using balloon dilatation, or treatment for recurrent respiratory papillomatosis (RRP) with radiofrequency cold ablation, in order to answer the research questions highlighted by NICE as absent from the current evidence base on each procedure (see guidance 1.3 in IPG425 and IPG434). Registry data will help to address this gap.

AIR has been collecting data on balloon dilatation for airway stenosis since 01/04/2015 and we are due to report back to NICE by 30/06/2018 to inform the IPG425 guidance update. As part of a national survey (Donne et al., 2016) we gathered clinical advice that radiofrequency cold ablation is not commonly used to treat RRP, and what was needed was safety and efficacy data gathered for all treatments for this condition. As RRP is such a rare disease we have extended data collection to include both adults and paediatrics. We secured funding from the NIHR's RfPB programme to support the development of the RRP registry in paediatrics, which will be hosted on the same AIR platform (both ENT procedures, same clinical staff entering data but different patient population). Funding was received on 1st September 2017 for a 3 year fixed period.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Newcastle and North Tyneside 1, 29/12/2014, IRAS ID: 164160, REC ref: 14/NE/1200

Study design

Observational; Design type: Cohort study

Primary study design

Observational

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Recurrent Respiratory Papillomatosis

Interventions

The trialists are collecting observational data on all interventions for RRP in a secure, online database over a 28-month period from 01/04/2018 to 31/08/2020. The objective is to improve the care of patients with RRP by analysing the registry data to determine which of the RRP interventions currently being used in UK NHS hospitals are the safest and most effective (information which is currently lacking).

By determining the most effective interventions for RRP, the trialists will be able to increase the time interval between surgical interventions to maintain symptomatic control, reduce overall number of RRP interventions, severity and spread of papillomas in the airway, hospital visits, medications and ultimately improve quality of life in those suffering from RRP. By also capturing peri- and post-procedural details they will be able to determine the relative safety of the

different interventions available and identify those which minimise the spread of disease. From the data collected they will also be able to identify patient subgroups (based on patient characteristics such as age, gender, human papillomavirus (HPV) type, location of papillomas, RRP severity and spread, comorbidities) who respond better to specific interventions, and also identify patient risk factors which contribute to the complication outcomes (such as tracheostomy).

Intervention Type

Other

Primary outcome(s)

1. Effectiveness of the interventions, assessed using the Derkey staging system to quantify RRP severity based on involvement of laryngeal structures. As this is observational data, the study will not require the patients to attend additional hospital appointments. They will be assessed at their routine hospital visits which will be scheduled according to clinical need over the course of the 28-month data collection period.
2. Quality of life, measured using the Voice Handicap Index (VHI) questionnaire (for patients aged 16 or over) or the paediatric Voice Handicap Index (pVHI) for patients under 16. Patients currently complete these questionnaires as part of their standard care at hospital appointments. Patients who have consented to taking part in the study will also be given a unique QoL ID so that they can submit additional QoL forms via a secure patient website at their convenience.

Key secondary outcome(s)

1. Peri-procedural complications; Timepoint(s): At hospital discharge
2. Airway related A&E visits; Timepoint(s): After hospital discharge
3. Airway related GP visits; Timepoint(s): After hospital discharge
4. Change in Derkey score (disease severity and spread); Timepoint(s): Over 28-month data collection period
5. Change in voice assessment scores; Timepoint(s): Over 28-month data collection period
6. Inter-surgical interval (time between interventions to achieve symptomatic control); Timepoint(s): Over 28-month data collection period
7. Nature and timing of surgical intervention; Timepoint(s): Over 28-month data collection period
8. Nature and timing of adjuvant therapy; Timepoint(s): Over 28-month data collection period
9. Histology results (including HPV type); Timepoint(s): Over 28-month data collection period
10. No. of hospital visits/admissions (inpatient, outpatient); Timepoint(s): Over 28-month data collection period
11. Post-operative discharge location (planned and actual); Timepoint(s): After procedure (following RRP intervention)

Completion date

31/08/2022

Eligibility

Key inclusion criteria

All patients (adults and paediatrics) with a diagnosis of RRP receiving at least one intervention for RRP in a UK NHS hospital

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

Key exclusion criteria

Patient/parent/guardian unable/unwilling to provide written informed assent/consent

Date of first enrolment

01/04/2018

Date of final enrolment

31/08/2022

Locations**Countries of recruitment**

United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre

Alder Hey Children's Hospital Liverpool

Liverpool

United Kingdom

L14 5AB

Study participating centre

Basildon & Thurrock University Hospitals NHS Foundation Trust

Basildon

United Kingdom

SS16 5NL

Study participating centre

Blackpool Teaching Hospitals NHS Foundation Trust

Blackpool
United Kingdom
FY3 8NR

Study participating centre

Great Ormond Street Hospital for Children NHS Foundation Trust

London
United Kingdom
WC1N 3JH

Study participating centre

North Cumbria University Hospitals NHS Trust

Carlisle
United Kingdom
CA2 7HY

Study participating centre

Nottingham University Hospitals NHS Trust

Nottingham
United Kingdom
NG5 1PB

Study participating centre

The Newcastle upon Tyne Hospitals NHS Foundation Trust

Newcastle
United Kingdom
NE7 7DN

Study participating centre

NHS Greater Glasgow and Clyde

Glasgow
United Kingdom
G12 0XH

Study participating centre

Aintree University Hospital NHS Foundation Trust
Liverpool
United Kingdom
L9 7AL

Study participating centre
Birmingham Children's Hospital NHS Foundation Trust
Birmingham
United Kingdom
B46NH

Study participating centre
Bradford Teaching Hospitals NHS FT
Bradford
United Kingdom
BD9 6RJ

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
City of Sunderland Hospitals NHS Foundation Trust
Sunderland
United Kingdom
SR4 7TP

Study participating centre
County Durham and Darlington NHS Foundation Trust
Durham
United Kingdom
DL3 6HX

Study participating centre

Derby Hospitals NHS Foundation Trust
Derby
United Kingdom
DE22 3NE

Study participating centre
Hywel Dda Health Board
Carmarthen
United Kingdom
SA31 3BB

Study participating centre
Isle of Wight NHS Trust
Newport
United Kingdom
PO30 5TG

Study participating centre
Leeds Teaching Hospitals NHS Trust
Leeds
United Kingdom
LS9 7TF

Study participating centre
Lewisham and Greenwich NHS Trust
London
United Kingdom
SE13 6LH

Study participating centre
London North West Healthcare NHS Trust
London
United Kingdom
HA1 3UJ

Study participating centre

Manchester University Hospitals NHS Foundation Trust
Manchester
United Kingdom
M13 9WL

Study participating centre
NHS Grampian
Aberdeen
United Kingdom
AB25 2ZB

Study participating centre
NHS Lothian
Edinburgh
United Kingdom
EH1 3EG

Study participating centre
Plymouth Hospitals NHS Trust
Plymouth
United Kingdom
PL6 8DH

Study participating centre
Salford Royal NHS Foundation Trust
Manchester
United Kingdom
M68 HD

Study participating centre
Sheffield Children's NHS Foundation Trust
Sheffield
United Kingdom
S10 2TH

Study participating centre

South Tees Hospitals NHS Foundation Trust
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
Wirral University Teaching Hospital NHS FT
Birkenhead
United Kingdom
CH49 5PE

Study participating centre
NHS Tayside
Dundee
United Kingdom
DD2 1GZ

Study participating centre
Abertawe Bro Morgannwg University Health Board
United Kingdom
SA12 7BR

Study participating centre
Barts Health NHS Trust
United Kingdom
E1 1BB

Study participating centre
Belfast Health and Social Care Trust
United Kingdom
BT2 8BG

Study participating centre
Betsi Cadwaladr University Health Board
United Kingdom
LL57 2PW

Study participating centre
Cardiff & Vale University Health Board
United Kingdom
CF14 4XW

Study participating centre
Doncaster And Bassetlaw Hospitals NHS Foundation Trust
United Kingdom
DN2 5LT

Study participating centre
East Sussex Healthcare NHS Trust
United Kingdom
BN21 2UD

Study participating centre
Frimley Park Hospital NHS Foundation Trust
United Kingdom
GU16 7UJ

Study participating centre
Imperial College
United Kingdom
W2 1NY

Study participating centre
Oxford University Hospitals NHS FT
United Kingdom
OX3 9DU

Study participating centre
Pennine Acute Hospitals NHS Trust
United Kingdom
M8 5RB

Study participating centre

St George's Healthcare NHS Trust
United Kingdom
SW17 0QT

Study participating centre
Stockport NHS Foundation Trust
United Kingdom
SK2 7JE

Study participating centre
The Shrewsbury and Telford Hospital NHS Trust
United Kingdom
SY3 8XQ

Study participating centre
University Hospital Birmingham NHS FT
United Kingdom
B15 2GW

Study participating centre
University College London Hospitals NHS Foundation Trust
United Kingdom
NW1 2PG

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

Sponsor information

Organisation
The Newcastle upon Tyne Hospitals NHS Foundation Trust

ROR
<https://ror.org/05p40t847>

Funder(s)

Funder type

Government

Funder Name

NIHR Central Commissioning Facility (CCF); Grant Codes: PB-PG-0416-20037

Results and Publications

Individual participant data (IPD) sharing plan

Any external researchers requesting data from the registry will be required to submit a formal application form describing which datafields are required, the time period of interest, if updates are required (i.e. monthly/annually), what the information will be used for and how the results of any analysis will be shared with the public. Only formal applications with appropriate ethical approvals in place (reviewed by an independent Ethics Committee) will be reviewed by the established AIR Steering Group committee. If successful, a data sharing agreement between applying researcher and Steering Group committee will be signed. If approval is given, only anonymised data will be shared for the purposes of external research studies.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		24/10/2024	25/10/2024	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Our experience in developing and operating the Airway Intervention Registry for Recurrent Respiratory Papillomatosis (AIR-RRP): national data collection	12/01/2023	19/07/2024	Yes	No
Participant information sheet	version v1.5	15/02/2018	12/06/2018	No	Yes
Protocol file	version V1.5	17/04/2018	12/06/2018	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes