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Quality of life effects of chickenpox on children and their families

Submission date
20/03/2019

Recruitment status
No longer recruiting

Registration date
25/03/2019

Overall study status
Completed

Last Edited
19/03/2024

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
Chickenpox is one of the commonest illnesses in childhood. For most children with mild disease it is unpleasant but other than a few scars they will have no long term consequences, however a small proportion will develop very severe potentially life threatening side effects.

Very effective vaccines exist against chickenpox and have been safely used in the rest of the world for over twenty years. However in the NHS new vaccines can only be introduced if they can be shown to be good value for money. The government body that assesses this, the Joint Committee for Vaccination and Immunisation (JCVI) examined the use of chickenpox vaccines in 2010 but advised against vaccine introduction. One of the main areas of uncertainty identified was the degree to which the quality of life of children and their parents is affected

Who can participate?
Children who have, have recently had, or have recently been exposed to chickenpox can take part in this study.

What does the study involve?
This study will collect more accurate data on the age distribution and impact on quality of life for children hospitalised by chickenpox and their families. To do this we will identify children with chickenpox in hospitals and the community and ask them and their parents to fill out short diary cards made up of standard quality of life survey tools . There will be no interventions, tests or hospital visits as part of the study – just completion of simple diaries.

What are the possible benefits and risks of participating?
None

Where is the study run from?
1. Bristol Children's Hospital, Bristol, UK
2. Hospital Pediátrico de Coimbra, Coimbra, Portugal

When is the study starting and how long is it expected to run for?
March 2018 to January 2023

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

Who is the main contact?
Dr. Robin Marlow, robin.marlow@bristol.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Robin Marlow

ORCID ID
http://orcid.org/0000-0002-3192-3102

Contact details
Level 6, UHBristol Education Centre
Upper Maudlin Street
Bristol
United Kingdom
BS2 8AE
0117 3420172
robin.marlow@bristol.ac.uk

Type(s)
Scientific

Contact name
Prof Fernanda Rodrigues

ORCID ID
http://orcid.org/0000-0002-5820-5215

Contact details
Centro Hospitalar e Universitário de Coimbra - Hospital Pediátrico
Coimbra
Portugal
3000-602
+351 239 488 700
rodriguesfmp@gmail.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
1.3

Study information

Scientific Title
Prospective cohort study of quality of life impact and healthcare usage in hospitalised and community cases of varicella zoster in children and their carers

Acronym
QoLPox

Study objectives
Whilst a ubiquitous disease of childhood with vaccines available to prevent it, chickenpox is not currently part of the UK or Portuguese childhood vaccine programme. Current evidence on the quality of life burden on children and their families is limited, we aim to follow a cohort of community and hospitalised cases of varicella to determine the QALY loss due to this disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Hospital arm approved 09/04/2018, East of Scotland Research Ethics Service (Ninewells Hospital & Medical School, Tayside Medical Science Centre (TASC), Residency Block, Level 3, George Pirie Way, Dundee, DD1 9SY; 01382 383848; eosres.tayside@nhs.net), ref: 18/ES/0040.
2. Community arm approved 22/01/2018, University of Bristol Faculty of Health Services Ethics (University of Bristol, Beacon House, Queens Road, Bristol, BS8 1QU, UK; 0117 928 9000; liam.mckervey@bristol.ac.uk), ref: 60721

Study design
International multi-centre cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Other

Study type(s)
Quality of life

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
Chickenpox

Interventions
Inpatient arm:
We will recruit patients with with acute varicella or secondary complications requiring admission to hospital. After informed consent they (child and both carers) will be asked to complete daily quality of life diaries whilst an inpatient. After discharge they will complete weekly diaries for one month with final follow up diary at 6m.
Community arm:
We will recruit patients with acute varicella in the community. After informed consent they (child and both carers) will be asked to complete daily diaries (alternate day quality of life) for 7-14 days until recovered to baseline.

Intervention Type
Other

Primary outcome measure
Total QALY loss due to varicella in children and carers, for child assessed with CHU9 & EQ5D-5L and for parent with EQ5D-5L. For inpatient arm this is measured daily until discharge, once weekly for first month and then again at 6m. For community arm this is measured alternate days (although there is a diary every day)

Secondary outcome measures
We will collect data on disease severity using a previously validated assessment of varicella symptoms tool (Vázquez et al 2001), demographics, healthcare use, illness within the family unit and missed work/education days. We will estimate the financial and societal costs for families through a daily diary inquiring about medication use, additional childcare costs and days of work missed.

Overall study start date
01/10/2017

Completion date
31/01/2023

Eligibility

Key inclusion criteria
1. Male or Female, less than 18 years old.
2. Hospital arm: Currently have chickenpox or have had it during the last 21 days (12m for stroke).
3. Community arm: History of close exposure to active case of chickenpox or diagnosis of early disease
4. Informed consent obtained from the parent(s) / guardian with assent in children >6 years.

Participant type(s)
All

Age group

Child

Upper age limit
18 Years

Sex
Both

Target number of participants
200

Total final enrolment
435

Key exclusion criteria
1. Only those for whom admission is felt to be clinically unrelated to recent varicella (e.g. injuries / new malignant diagnosis) should be excluded from the study.

Date of first enrolment
01/03/2018

Date of final enrolment
01/12/2021

Locations

Countries of recruitment
England

Portugal

United Kingdom

Study participating centre
Bristol Children's Hospital
Upper Maudlin Street.
Bristol
United Kingdom
BS2 8AE

Study participating centre
Hospital Pediátrico de Coimbra
Aevnida, R. Dr. Afonso Romão,
Coimbra
Portugal
3000-602

Sponsor information

Organisation
University of Bristol

Sponsor details
Research and Enterprise Development
University of Bristol
One Cathedral Square
Bristol
England
United Kingdom
BS1 5DD
0117 428 4011
research-governance@bristol.ac.uk

Sponsor type
University/education

Website
www.bristol.ac.uk/red

ROR
https://ror.org/0524sp257

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
It is anticipated that this research will lead to publications in a journals covering the areas of paediatric infectious disease or vaccine research. Interim results are planned to be shared with the JVCI and presented at the ESPID summer 2020 meeting with final results in 2020.

Participating families will be asked if they would like to receive a copy of the final report.

Intention to publish date
01/06/2023

Individual participant data (IPD) sharing plan
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
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		29/03/2023	30/03/2023	Yes	No
HRA research summary			28/06/2023	No	No
Protocol file	Protocol for hospital arm only version 1.5	27/11/2019	20/11/2023	No	No
Basic results			19/03/2024	No	No