ISRCTN48257441 https://doi.org/10.1186/ISRCTN48257441

PEPtalk 2: Pilot of a randomised controlled trial to compare VZIG and aciclovir as post-exposure prophylaxis against chickenpox in children with cancer

Submission date 08/11/2013	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 08/11/2013	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 22/01/2019	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol
http://www.cancerresearchuk.org/cancer-help/trials/a-study-looking-at-vzig-or-aciclovir-for-children-who-have-been-exposed-to-chicken-pox-during-cancer-treatment-peptalk2

Contact information

Type(s)
Scientific

Contact name
Mr Stephen Baker

Contact details
Cancer Research UK Clinical Trials Unit
Institute for Cancer Studies, Edgbaston
Birmingham
United Kingdom
B15 2TT
-
peptalk2@trials.bham.ac.uk

Additional identifiers

EudraCT/CTIS number
2013-001332-22

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
15060

Study information

Scientific Title
PEPtalk 2: Pilot of a randomised controlled trial to compare VZIG and aciclovir as post-exposure prophylaxis against chickenpox in children with cancer

Acronym
PEPtalk 2

Study objectives
Treatment for cancer in children often includes the use of anti-cancer drugs called chemotherapy. Some chemotherapy drugs can reduce the production of white blood cells, which lowers a child's immunity. This means that some infections that are usually mild in healthy children can be more difficult for a child with cancer to cope with. Chickenpox is one of these infections and it can be life-threatening for a child with cancer.

It is therefore important to try to prevent children with cancer from developing chickenpox. If a child with cancer has close contact with someone who is infectious for chickenpox, they are usually offered preventative medicine. This is called post-exposure prophylaxis (PEP). There are two different types of PEP used in the UK and medical opinion is divided over which is better. So about half of children receive VZIG, an injection of chickenpox antibodies into the muscle, while the other half of children receive aciclovir, an orally administered course of antiviral medicine.

This pilot trial aims to prepare for a main Phase III trial, the aim of which will be to find out whether aciclovir is at least as good as VZIG in protecting against chickenpox in children with cancer. This pilot study will help to inform a sample size calculation; it will test the components of the larger study; and it will test how acceptable the trial procedures are to parents, patients and clinicians. A secondary aim is to establish whether these two treatments have different costs to the health service and the effects on patients quality of life. A health economic analysis will be performed accordingly.

Ethics approval required
Old ethics approval format

Ethics approval(s)
13/LO/0551; First MREC approval date 14/05/2013

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Topic: National Cancer Research Network, Medicines for Children Research Network; Subtopic: All Cancers/Misc Sites, All Diagnoses; Disease: All, All Diseases

Interventions
Trial Treatment, Both trial arms are 'standard' treatments although which is the standard varies from one centre to another. Some patients may therefore receive an intramuscular injection, by way of the trial treatment, in circumstances where they would more commonly receive oral therapy, and vice versa. The potential risks and discomfort associated with both therapies are explained in the Parent/Patient Information Sheets and clinicians will also explain these to parents and (where possible) patients when takin

Intervention Type
Other

Phase
Phase II/III

Primary outcome measure
The number of patients randomised within 12 months of the trial

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2014

Completion date
31/12/2015

Eligibility

Key inclusion criteria
For registration:
1. Under 16 years of age
2. EITHER diagnosed with cancer such that there is a standard expectation of immunocompromising therapy OR currently receiving immunocompromising treatment for cancer OR within 3 months of having received immunocompromising treatment for cancer
3. No current or previous allogeneic or autologous haemopoietic stem cell transplantation / rescue

4. Negative VZV serostatus result at cancer diagnosis or negative VZV serostatus result within the last 3 months as assessed locally
5. Written informed consent to registration received from parent/legal representative and, where appropriate, written patient assent

For randomisation:
1. Patient has previously been registered in the PEPtalk2 trial, having satisfied all registration requirements
2. Registration criterion (c) continues to apply
3. Immunocompromising treatment for cancer must have been initiated prior to VZV exposure
4. Patient is able to commence either VZIG no more than 10 days after experiencing VZV exposure, or aciclovir at 7 days after experiencing VZV exposure (see sections 5.1.2 and 5.1.3)
5. No renal impairment. Renal impairment is expressed in terms of glomerular filtration rate (ml /min/1.73m2). Child over 1 year: Estimated glomerular filtration rate (ml/min/1.73m2) = 40 x height (cm) x serum creatinine (micromol/litre). Normal renal function: > or equal to 90ml /min/1.73m2
6. Written informed consent to randomisation received from parent/legal representative and, where appropriate, written patient assent

Important note regarding thrombocytopenia: platelets must be > 50 x 109/L to receive an intramuscular injection of VZIG. Therefore, if a child is randomised to receive VZIG and platelets are found to be < 50 x 109/L no more than 48 hours prior to VZIG administration, arrangements must be made by local staff to administer a platelet transfusion prior to VZIG injection. There are no criteria for platelet count if randomised to acyclovir.

Participant type(s)
Patient

Age group
Child

Upper age limit
16 Years

Sex
Both

Target number of participants
Planned Sample Size: 50; UK Sample Size: 50

Key exclusion criteria
Exclusion from Registration:
1. 16 years of age or over
2. Current or previous allogeneic or autologous haemopoietic stem cell transplant/rescue
3. Positive VZV serostatus result as assessed locally within the last 3 months
Note: renal impairment and thrombocytopenia are not absolute contraindications for registration as they might resolve by the time a chickenpox exposure and screening for randomisation occur

Exclusion from randomisation:
1. Positive VZV serostatus result at time of screening

2. Contraindication to either aciclovir or VZIG, including:
2.1. thrombocytopenia (platelets < 50 x 109/L) that has not been corrected by platelet transfusion
2.2. renal impairment (exclude any child with GFR below 90ml/min/1.73m2)
2.3. any other contraindications deemed to be relevant by the local Investigator or the Sponsors Clinical Coordinator(s)
3. Inability to start either VZIG within 10 days of VZV exposure, or acyclovir at 7 days after VZV exposure
4. More than one VZV exposure within the past 12 weeks
5. Inability to tolerate medications via oral or enteral route
6. Pregnancy or lactation

Date of first enrolment
01/01/2014

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Cancer Research UK Clinical Trials Unit
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
University of Birmingham (UK)

Sponsor details
Birmingham Clinical Trials Unit
Division of Cancer Studies
Robert Aitken Institute
, Edgbaston
Birmingham
England
United Kingdom
B15 2TT

Sponsor type
University/education

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2019	22/01/2019	Yes	No
HRA research summary			28/06/2023	No	No