

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

<b>Submission date</b> 08/11/2013	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 08/11/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 22/01/2019	<b>Condition category</b> Cancer	<input type="checkbox"/> 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

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## 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 taking

**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/1.73m<sup>2</sup>). Child over 1 year: Estimated glomerular filtration rate (ml/min/1.73m<sup>2</sup>) = 40 x height (cm) x serum creatinine (micromol/litre). Normal renal function: > or equal to 90ml/min/1.73m<sup>2</sup>
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 10<sup>9</sup>/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 10<sup>9</sup>/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 10<sup>9</sup>/L) that has not been corrected by platelet transfusion
  - 2.2. renal impairment (exclude any child with GFR below 90ml/min/1.73m<sup>2</sup>)
  - 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

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**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?
<a href="#">Results article</a>	results	01/01/2019	22/01/2019	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No