ISRCTN71445600 https://doi.org/10.1186/ISRCTN71445600

Study to see if steroids reduce kidney problems in Henoch Schonlein purpura

Submission date
30/10/2011

Recruitment status
No longer recruiting

Registration date
30/11/2011

Overall study status
Completed

Last Edited
06/01/2014

Condition category
Haematological Disorders

[ ] Prospectively registered

[ ] Protocol

[ ] Statistical analysis plan

[X] Results

[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Henoch Schonlein Purpura (HSP) is a rare condition that happens mostly in children where there is inflammation of small blood vessels. This causes a rash, stomach pains and joint pains and swelling, usually of the ankles and feet. HSP also commonly causes the kidneys to leak small amounts of blood or protein into the urine. About one in 20 patients will have serious kidney problems due to HSP. It is possible that treatment with tablets called steroids, may help to prevent children from developing kidney disease. This study aims to find out whether treatment with a steroid (called prednisolone) can prevent or reduce the kidney complications of HSP.

Who can participate?
Children and young people up to the age of 18 with a diagnosis of HSP are invited to take part in the study.

What does the study involve?
Children and young people with HSP will be assigned to receive either a steroid in the form of a tablet or syrup, or a preparation that contains no medicinal products. Parents, patients and doctors will not be told of the type of treatment allocated, so as to avoid any bias. The tablets / liquid must be taken daily for 14 days and must be started within 7 days of the onset of the rash. As part of the study protocol all children with Henoch Schonlein Purpura (HSP) will be seen in the hospital 4 weeks, 3 months and 12 months after the first presentation. At these visits we will take the blood pressure and check the urine for protein and blood. In addition, all patients should be seen either by the GP or at the local hospital for blood pressure and urine checks weekly for the first 4 weeks. Those who develop kidney complications will be followed up for as long as these problems persist.

What are the possible benefits and risks of participating?
During the research project Children and young people with HSP will be very closely monitored, and receive regular check-ups including routine urine testing. It is possible, that treatment with steroids, may help to prevent children and young people with HSP from developing kidney disease. Side effects of steroids are very unlikely for such a short course, but may include stomach upset (nausea, vomiting (which may be blood stained) or loss of blood from the back passage) and feeling faint. These symptoms may also be seen in untreated HSP

Where is the study run from?
The study will take place in 29 hospitals in England and Wales. The lead centre was University Hospital of Wales, Cardiff (UK).

When is the study starting and how long is it expected to run for?
The study will start in January 2001 and end in January 2005.

Who is funding the study?
The study is funded by Wales Office of Research and Development for Health and Social Care (UK).

Who is the main contact?
Dr Jan Dudley
jan.dudley@nhs.net

Contact information

Type(s)
Scientific

Contact name
Dr Jan Dudley

Contact details
Department of Paediatric Nephrology
Bristol Royal Hospital for Children
Bristol
United Kingdom
BS28BJ

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
R99/1/020

Study information

Scientific Title
Randomised, placebo-controlled trial to assess the role of early prednisolone on the development and progression of Henoch Schonlein purpura nephritis

Study objectives
Prednisolone would reduce the prevalence of proteinuria at a set point (12 months) after initial presentation of Henoch-Schonlein purpura

Ethics approval required
Old ethics approval format

Ethics approval(s)
Multicentre Research Ethics Committee approved on 14 December 1998, ref: MREC/98/6/68

Study design
Randomised double-blind placebo-controlled multi-centre study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Henoch Schonlein Purpura

Interventions
Prednisolone 2mg/Kg/d (max 80mg) versus placebo for 7 days, then 1mg/kg/day for 7days to complete a 14 day course.

Follow-up 1 year from baseline visit

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Prednisolone

Primary outcome measure
1. The presence of proteinuria at 12 months (defined as urine protein: creatinine ratio (UP:UC) >20mg/mmol)
2. The need for additional treatment (defined as the presence of hypertension (requiring treatment) and / or renal biopsy anomalies and / or the need for treatment of renal disease) during the 12 month study period
3. The association of polymorphisms of the ACE gene with proteinuria at 12 months

Secondary outcome measures
Presence of symptoms of possible trial medication induced toxicity: hypertension and/or gastrointestinal (GI) upset

Overall study start date
01/01/2001

Completion date
31/01/2005

Eligibility

Key inclusion criteria
Children under 18 years of age presenting to secondary care centres in England and Wales with a diagnosis of Henoch-Schönlein Purpura (HSP), based on the American College of Rheumatology Criteria

Participant type(s)
Patient

Age group
Child

Upper age limit
18 Years

Sex
Both

Target number of participants
368

Key exclusion criteria
1. Those already receiving steroid / immunosuppressive therapy
2. Those receiving Angiotensin converting enzyme (ACE) inhibitors
3. Those with pre-existing renal disease (excluding urinary tract infections)
4. Those with pre-existing hypertension
5. Those with evidence of immunodeficiency /systemic infection
6. Those with contra-indications or relative contra-indications for steroid therapy (epilepsy, diabetes mellitus, glaucoma or peptic ulceration)
7. Those with characteristic purpuric rash for more than 7 days

Date of first enrolment
01/01/2001

Date of final enrolment
31/01/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Paediatric Nephrology
Bristol
United Kingdom
BS28BJ

Sponsor information

Organisation
University Hospital of Wales NHS Trust (UK)

Sponsor details
c/o Mr Paul Davies
Heath Park
Cardiff
Wales
United Kingdom
CF144XW

Sponsor type
Hospital/treatment centre

Website
http://www.cardiffandvaleuhb.wales.nhs.uk/

ROR
https://ror.org/04fgpet95

Funder(s)

Funder type
Government

Funder Name
Wales Office of Research and Development for Health and Social Care (UK) (ref: R99/1/020)

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	01/10/2013		Yes	No