Ferriprive anemia in patients with erythropoietic protoporphyria

Published: 26-07-2007
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To investigate the prevalence of anemia in EPP patients, related to the severity of symptoms and to investigate the cause of this anemia.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Metabolic and nutritional disorders congenital
Study type	Observational invasive

Summary

ID

NL-OMON31219

Source
ToetsingOnline

Brief title
Iron, anemia and protoporphyria

Condition

- Metabolic and nutritional disorders congenital
- Inborn errors of metabolism
- Epidermal and dermal conditions

Synonym
cutaneous porphyria, EPP

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Anemia, Iron, Protoporphyria

Outcome measures

Primary outcome

The primary study variables are:

- The amount of protoporphyrin, the activity of the enzyme ferrochelatase,

the liver functions and the score of the quality of life

questionnaire show

the gravity of the symptoms of EPP

- The presence or not of a low amount of hemoglobin

- The presence or not of iron deficiency

Secondary outcome

n.a.

Study description

Background summary

There is much difference in severity of symptoms of patients with erythropoietic protoporphyria (EPP). There have been various studies to find the cause for this difference. The difference in severity might be partly explained by the presence or not of a low amount of hemoglobin. Recent research has been performed to investigate the role of iron in EPP. An important observation is that part of the patients with EPP has iron deficiency, which might cause the anemia.
If actually can be confirmed that an iron deficiency is the base of anemia in patients with EPP, these patients can be given iron suppletion, which can reduce the severity of symptoms.

Study objective

To investigate the prevalence of anemia in EPP patients, related to the severity of symptoms and to investigate the cause of this anemia.

Study design

Blood (via venapunction) will be investigated for a possible anemia, a possible iron deficiency, the amount of protoporphyrin and liver function. Patients with anemia and iron deficiency will be given low doses of iron after consideration with the general practitioner. After 3 months they will be examined again to investigate any effects.
Furthermore the investigators will notice the severity of the symptoms with a quality of life questionnaire. Also information about food, medication, alcohol use and smoking will be collected.

Study burden and risks

The only disadvantage which can be the consequence of this study, is that as result of the venapunction the patients can get an haematoma.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Known diagnosis of erythropoietic protoporphyria
- age = 18 years or older

Exclusion criteria

none

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-08-2007
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	26-07-2007

Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL18022.078.07