Follow-up Safety Trial in children with chronic heart failure therapy receiving Orodispersible Minitablets of Enalapril (WP10 Trial).

Published: 12-10-2015
Last updated: 19-04-2024

Primary:To demonstrate the safety of enalapril Orodispersible Minitablets (ODMTs).Secondary:1. To describe the acceptability and palatability of enalapril ODMTs..2. To collect additional information about pharmacokinetics and pharmacodynamics of…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON46324

Source
ToetsingOnline

Brief title
WP10 trial

Condition

- Other condition
- Congenital cardiac disorders

Synonym
Congenital Heart Disease, Dilated Cardiomyopathy

Health condition

hartaandoeningen, myocardaandoeningen

Research involving
Human

Sponsors and support

Primary sponsor: Ethicare GmbH
Source(s) of monetary or material Support: LENA consortium door financiering van de Europese Unie.

Intervention

Keyword: Enalapril, Heart failure, Paediatrics, Safety follow-up

Outcome measures

Primary outcome

Any adverse events.

Secondary outcome

1. Blood pressure in paediatric patients under and after enalapril ODMT

treatment.

2. Renal function in paediatric patients under and after enalapril ODMT

treatment.

3. Exploratory pharmacokinetics and pharmacodynamics in paediatric patients

under enalapril ODMT treatment.

4. Acceptability and palatability of the novel formulation in paediatric

patients under enalapril ODMT treatment.

5. Rehospitalisation due to heart failure including the need for heart

transplantation or the institution of mechanical circulatory support.

6. Death due to worsening of the underlying disease.

7. Echocardiography (Shortening Fraction).

Study description

Background summary

Enalapril maleate has established medical use having been marketed in Europe since 1983. Its safety and efficacy in adults are therefore well understood, although less so in paediatric patients since few clinical studies have been conducted in this population. The European Medicines Agency Expert Group Meeting on Paediatric Heart Failure considers enalapril a first-line treatment for chronic heart failure in children (EMA, 2010a).
There is currently no licensed formulation of enalapril available in Europe suitable for use in children with heart failure, resulting in the administration of extemporaneous oral preparations. This study will enable the development of a novel clinically relevant age-appropriate and acceptable enalapril formulation, with improved method of administration and ease of dosing compared to products currently available.

Study objective

Primary:
To demonstrate the safety of enalapril Orodispersible Minitablets (ODMTs).

Secondary:
1. To describe the acceptability and palatability of enalapril ODMTs..
2. To collect additional information about pharmacokinetics and pharmacodynamics of enalapril ODMTs during long term treatment.

Study design

Fase II/III Prospective open-label multi-centre extension safety study in infants and children.

Intervention

nvt

Study burden and risks

nvt

Contacts

Public
Ethicare GmbH

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DE
Scientific
Ethicare GmbH

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

-Patients from the WP08 and WP09 trials who have been treated with enalapril Orodispersible Minitablets and are still under ODMT treatment.
-Patients from the WP08 and WP09 trials who have been treated for at least 3 days with enalapril Orodispersible Minitablets and are not anymore under ODMT treatment.
-Patient and/or parent(s)/legal representative provided written informed consent for participation in this long term follow-up study and assent is received from the patient according to national legislation and as far as achievable from the child.

Exclusion criteria

Patients who have been enrolled and treated in the WP08 or WP09 trials have fulfilled the respective in- and exclusion criteria of those protocols. As it is the aim of this Follow-up Study to observe the safety of all patients exposed to enalapril ODMT treatment, no additional exclusion criteria are defined in this protocol.

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-03-2016
Enrollment:	11
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Enalapril orodispersible minitablet 0,25mg
Generic name:	Enalapril Maleate orodispersible minitablet 0,25mg
Product type:	Medicine
Brand name:	Enalapril Orodispersible minitablet 1,0mg
Generic name:	Enalapril Maleate orodispersible minitablet 1,0mg

Ethics review

Approved WMO Date:	12-10-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	04-12-2015
Application type:	First submission

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	23-03-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	24-03-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	02-02-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	02-11-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-11-2017
Application type:	Amendment
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
EudraCT	EUCTR2015-002397-21-NL
CCMO	NL54931.078.15