

Subcutaneous immunoglobulins with rHuPH20 in multifocal motor neuropathy

Published: 30-11-2015

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To study whether hyqvia is as effective, safe and tolerable (or more tolerable) as IVIg.

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

Summary

ID

NL-OMON44726

Source

ToetsingOnline

Brief title

Hymne

Condition

- Peripheral neuropathies

Synonym

disease of nerves caused by the immune system, inflammatory neuropathy

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum

Source(s) of monetary or material Support: Baxter, Universitair Medisch Centrum Utrecht, via de betreffende zorgverzekering van de patient

Intervention

Keyword: immunoglobulins, MMN, rHuPH20, subcutaneous

Outcome measures

Primary outcome

Safety/tolerability of hyqvia compared to IVIg

Clinical effect of hyqvia compared to IVIg.

Secondary outcome

none

Study description

Background summary

Multifocal motor neuropathy (MMN) is an immune mediated neuropathy that shows a progressive asymmetric weakness of the muscles in the hands and arms and feet to a lesser extend. The differentiation with fatal diseases as amyotrophic lateral sclerosis (ALS) is for many reasons essential. One of the reasons is that for MMN there is a treatment consisting of repeated infusions of immunoglobulins (IVIg). This does not cure MMN, but will reach stability to a slow progression in weakness over many years. On average, patients get their IVIg once every 2-4 weeks. Unfortunately in 20-40% of the infusions side effects are seen, locally and systematically. Examples are headache, skin reactions and gastro intestinal side effects. Usually this can be countered by applying secondary medication, but the repeated character is very burdensome for patients and affects their quality of life.

More recent subcutaneous immunoglobulins (SCIg) are available. This reduces (probably by different pharmacokinetic properties) the side effects and has in small clinical trials similar effects as IVIg.

A problem is the limited volume per infusion that can be given. To solve this problem, a combination of medication (Hyqvia) is at hand. It consists of an enzyme (hyaluronidase; rHuPH20) and immunoglobulins. rHuPH20 splices subdermal structures creating space for larger volumes of SCIg.

This is already approved in immunodeficiency diseases and certain malignancies (multiple myeloma and chronic lymphatic leukemia).

It is not known whether Hyqvia is effective and tolerable in MMN.

Study objective

To study whether hyqvia is as effective, safe and tolerable (or more tolerable) as IVIg.

Study design

Monocenter cross-over intervention study

Intervention

IVIg is switched into hyqvia.

Study burden and risks

Burden:

3 times venapuncture

questionnaires each visit of the outpatient clinic

Two hospitalizations of one day to start the switch to hyqvia (is done in every patient that begins with IVIg in our department). After that follow up is done in the outpatient clinic. The relatively high frequency of visits of the outpatient clinic is not uncommon in MMN patients and therefore not considered a clear EXTRA burden. It is and will be, however, a burden.

By switching to a subcutaneous infusion pharmacokinetics change and this can have impact on the functioning of a patient. This will be very detailed monitored in the successive outpatient visits. If necessary hyqvia dosing can be raised of a reswitch can be done to IVIg.

Risks:

A possible risk/change compares to the current treatment is the addition of rHuPH20. There is already a much data of patients with immunodeficiencies that use hyqvia. No major problems have been seen. Antibodies against rHuPH20 are seen, no neutralizing anti-rHuPH20 antibodies are detected. Cumulative risks are estimated low.

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

- Fulfilling the EFNS/PNS criteria of probable or definite MMN
- Age ≥ 18 years.
- Stable on IVIG maintenance treatment in the year preceding the study.

Exclusion criteria

- Treatment with other immunosuppressive drugs (cyclophosphamide, azathioprine, cyclosporine) in the 6 months preceding the study.
- Female patient who is pregnant or breast-feeding or of childbearing potential.

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated):	03-11-2016
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	HyQvia
Generic name:	Immunoglobulins combined with rHuPH20
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO	
Date:	30-11-2015
Application type:	First submission
Review commission:	METC NedMec
Approved WMO	
Date:	26-07-2016
Application type:	First submission
Review commission:	METC NedMec
Approved WMO	
Date:	14-03-2017
Application type:	Amendment
Review commission:	METC NedMec

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	EUCTR2015-000828-28-NL
CCMO	NL52642.041.15

Study results

Date completed:	28-02-2018
Actual enrolment:	18

Summary results

Trial is ongoing in other countries