IgM (anti-MAG) peripheral Neuropathy: from proper assessments to trial needs (IMAGiNe study).

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Plasma cell neoplasms
Study type	Observational non invasive

Summary

ID

NL-OMON45839

Source
ToetsingOnline

Brief title
IMAGiNe study

Condition

- Plasma cell neoplasms
- Autoimmune disorders
- Peripheral neuropathies

Synonym
IgM monoclonal gammopathy associated polyneuropathy, nerve disorder

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: GBS/CIDP Foundation International

Intervention

Keyword: IgM anti-MAG, MGUS, outcome measures, peripheral neuropathy

Outcome measures

Primary outcome

Data collection will be based on the formats derived from the Dutch ALS and IGOS studies. The following study parameters will be of interest: weakness ((RT)- MRC sum score), sensibility ((RT)- Modified ISS), disability (MGUSP-RODS), ataxia (MICARS/SARA), quality of life (EuroQol EQ-5D Health Questionnaire), pain (Pain-Intensity Numerical Rating Scale).

Secondary outcome

-

Study description

Background summary

IgM monoclonal gammopathy associated polyneuropathy (MGUSP) is slowly progressive with differential effects in individuals ranging from mild foot numbness and minor imbalance to severe neuropathic pain and sensory and motor dysfunction. Since all trials performed in monoclonal gammopathy of undetermined significance (MGUS) associated polyneuropathy had negative results, many questions need to be resolved before attempting other treatments. Suggested potential factors contributing to the negative results are: repeated use of suboptimal outcome measures, small trial sizes and low numbers of treated patients, the indolent disease course needing a longer follow-up period to capture relevant changes, or the possibility that administered treatments were not aggressive enough. So far there is no international consensus regarding how to assess and treat patients with IgM monoclonal gammopathy polyneuropathy. The IMAGiNe study will result in a unique collection of prospectively collected and highly standardized clinical data and a biobank from a large population of well-defined patients with IgM monoclonal gammopathy associated polyneuropathy. This data will be used to optimize the diagnostic

criteria for possible subtypes, to identify biomarkers to monitor and predict disease activity and response to treatment, and to predict models for treatment response and outcome in individual patients.

Study objective

The main objective is to describe in detail the variation in clinical subtypes, clinical course, past and current practice of treatment, antibody titers, and clinical picture of IgM monoclonal gammopathy associated polyneuropathy at the various levels of assessing outcome. The study group aims to define the clinical and biological determinants and predictors of this variation in subtypes, disease activity, treatment response and outcome. In achieving this a MGUS-specific Rasch-built overall disability scale (MGUS-RODS) will be constructed from obtained observational data that should fulfill all modern clinimetric requirements, including cross-cultural validity.

Study design

International, multi-center, prospective observational cohort study with a duration of 3 years (assessments at 0/6/12/24/36 months, plus visits in case the patient makes extra hospital visits during the study period). The coordinating centers will be the Maastricht University Medical Center and University Medical Center Utrecht, both in the Netherlands.

Study burden and risks

At study entry data will be collected regarding: (1) key clinical features and results from routine diagnostic work-up, (2) patient history, demography and current clinical situation defined by patients* complaints, neurological deficits and various outcome measures, (3) past treatments and treatment at study entry as well as the clinical response to those treatments, (4) bone marrow biopsy collected at diagnosis, if available. During the study patients will visit a total of five times. Four of these visits will be combined with the regular yearly appointment (t=0, t=12, t=24, t=36 months). During these regular yearly appointments patients undergo blood tests. During three of these vena punctures (t=0, t=12 and t=36 months) extra blood will be obtained for storage in a biobank. During all six visits physical examination will be performed including determining the (RT)-MRC sum score and (RT)-Modified ISS, and patients fill in the MGUS-RODS.

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 international criteria for the diagnosis IgM monoclonal gammopathy and peripheral neuropathy
- age 18 years or older
- written informed consent given by the participant

Exclusion criteria

- having concomitant diseases possibly interfering with peripheral nerve and function, as well as physical functioning, such as diabetes, renal insufficiency, prior treatment with chemotherapy for diseases other than their IgM monoclonal gammopathy associated peripheral neuropathy, alcohol abuse (more than 5 IU/day);
- having severe, active malignancy with poor prognosis, undergoing treatment aside from monoclonal gammopathy associated peripheral neuropathy;
- pregnancy
- use any medication that may influence peripheral nerve function.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-08-2016
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	08-06-2016
Application type:	First submission
Review commission:	METC NedMec

Approved WMO

Date:	11-01-2017
Application type:	Amendment
Review commission:	METC NedMec

Approved WMO

Date:	18-10-2017
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
CCMO	NL56244.041.16

Study results

Date completed:	05-05-2022
Actual enrolment:	103