Epidemiology of Anti-JCV Antibody Prevalence in Multiple Sclerosis Patients: JEMS

Published: 08-11-2010
Last updated: 03-05-2024

The objective of the study is to estimate the prevalence of anti-JCV antibodies in MS patients,including the following criteria:* Age* Gender* Race* Country of birth and the duration of residence* Current country of residence and the duration of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Central nervous system infections and inflammations
Study type	Observational invasive

Summary

ID

NL-OMON34210

Source
ToetsingOnline

Brief title
JEMS

Condition

- Central nervous system infections and inflammations

Synonym
disorder of the central nervous system, Multiple Sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Biogen
Source(s) of monetary or material Support: farmaceutische industrie

Intervention

Keyword: Anti-JCV Antibody, Epidemiology, Multiple Sclerosis

Outcome measures

Primary outcome

Prevalence of anti-JCV antibodies will be estimated as the number of patients

with anti-JCV

antibodies detected in serum divided by the total number of patients with a

serum sample that

was evaluated. Prevalence of anti-JCV antibodies will also be estimated by the

criteria described

in the objective of the study.

Secondary outcome

Not applicable

Study description

Background summary

Biogen Idec Inc. (Biogen Idec) has developed an analytically validated enzyme-linked
immunosorbent assay (ELISA) to detect the presence of JCV antibody in serum. Available data
with this assay, evaluating a geographically diverse subset of the multiple sclerosis (MS)
population, consisting of over 800 patients, indicate that the prevalence of anti-JCV-specific
antibodies (i.e., seroprevalence) is 53.6% with a 95% confidence interval (CI) of 49.9% to
57.3%, and an annual rate of seroconversion (i.e. change from anti-JCV antibody negative to
anti-JCV antibody positive status) of approximately 2%, and a false negative rate of 2.5%

(unpublished data). The prevalence of anti-JCV antibodies requires confirmation in the MS
population as a whole.

Study objective

The objective of the study is to estimate the prevalence of anti-JCV antibodies in MS patients,
including the following criteria:
* Age
* Gender
* Race
* Country of birth and the duration of residence
* Current country of residence and the duration of residence
* Country of longest residence
* Type and duration of MS
* Prior and current immunomodulatory and immunosuppressant therapies for MS and the duration of these MS therapies
* Prior and current immunomodulatory and immunosuppressant therapies not for MS and the duration of such therapies

Study design

This is a cross-sectional, multicenter, multinational, epidemiological study.

Study burden and risks

not applicable, study is non-invasive

Contacts

Public
Biogen

Innovation House, 70 Norden Road
Maidenhead Berkshire SL6 4AY
GB
Scientific
Biogen

Innovation House, 70 Norden Road
Maidenhead Berkshire SL6 4AY
GB

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

All candidates for this study must have the ability to understand the purpose of the study and provide signed and dated informed consent.
All patients with a diagnosis of MS of any type, irrespective of their treatment, are eligible to participate once.

Exclusion criteria

All candidates not able to understand the purpose of the study and not able to provide signed and dated informed consent.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	31-01-2011
Enrollment:	190
Type:	Actual

Ethics review

Approved WMO Date:	08-11-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL33336.029.10