ISRCTN78466206 https://doi.org/10.1186/ISRCTN78466206

The quality of life of multiple sclerosis patients in Europe

Submission date
06/08/2019

Recruitment status
No longer recruiting

Registration date
13/08/2019

Overall study status
Completed

Last Edited
14/04/2021

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
The HORIZON 2020 (H2020) Optogenerapy project aims to develop a new medical implant for the controlled release of beta interferon (IFN-β) treatment into the body for treating Multiple Sclerosis (MS) patients. By replacing standard interferon delivery with this implant the aim is to improve treatment effectiveness with fewer side effects and lower healthcare costs, improving the quality of life of MS patients. The aim of this study is to measure the current quality of life and health status of MS patients.

Who can participate?
Patients aged 18 and over with MS

What does the study involve?
The survey asks questions about participants' disease, treatment, health status and quality of life. They only have to fill in the survey once and it takes about 15-20 minutes to fill out.

What are the possible benefits and risks of participating?
There are no physical, legal or economic risks associated with participation in this study. Participants do not have to answer questions that they do not wish to answer. Participation is voluntary and can stop at any time.

Where is the study run from?
Erasmus School of Health Policy & Management at the Erasmus University Rotterdam (Netherlands)

When is the study starting and how long is it expected to run for?
January 2019 to October (updated 19/08/2020, previously: December 2019)

Who is funding the study?
European Union Horizon 2020

Who is the main contact?
L.A.Visser
l.a.visser@eshpm.eur.nl

Contact information

Type(s)
Public

Contact name
Mrs Laurenske Visser

ORCID ID
https://orcid.org/0000-0002-1478-813X

Contact details
Bayle Building
Burgemeester Oudlaan 50
Rotterdam
Netherlands
3062 PA
+31 (0)10 408 8648
l.a.visser@eshpm.eur.nl

Additional identifiers

Protocol serial number
MEC-2018-1636

Study information

Scientific Title
The quality of life of multiple sclerosis patients in Europe

Acronym
QOLMSE

Study objectives
The aim of this study is to asses the current quality of life and health status of multiple sclerosis patients in five European countries (including the United Kingdom, the Netherlands, France, Germany and Italy).

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 28/01/2019, The Erasmus MC Medical Ethics Review Committee (Postbus 2040, 3000 CA Rotterdam, Tel: +31 (0)10 7033625 extension nr 34428; Email: metc@erasmusmc.nl), ref: MEC-2018-1636

Primary study design
Observational

Study design
Observational cross-sectional survey

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Multiple sclerosis

Interventions
The online questionnaire consists of questions about patient demographics, clinical characteristics, quality of life measures (using the multiple sclerosis quality of life (MSQOL)-54), health state (using the EuroQol 5 Dimensions (EQ-5D-5L)). The questionnaire will be made available in five languages (Dutch, French, English, German and Italian). Official translations of the MSQOL-54 and EQ-5D-5L will be used and the remaining questions will be translated. Patients that choose to participate in the questionnaire will only have to fill it out once.

Intervention Type
Other

Primary outcome(s)
1. Quality of life measured using MSQOL-54
2. Health status measured using EQ-5D-5L
Both outcomes measured at a single timepoint, when the participant fills out the questionnaire

Key secondary outcome(s)
Clinical and treatment characteristics, measured by questionnaire at a single timepoint, when the participant fills out the questionnaire

Completion date
01/10/2019

Eligibility

Key inclusion criteria
1. Patients diagnosed with clinically definite multiple sclerosis (relapsing-remitting MS, secondary progressive MS, primary progressive MS)
2. Age 18 years or older
3. No restrictions whether patients are or are not using immunomodulatory therapy, or have used other therapies in the past
4. Participants have to have access to internet and the OPTOGENERAPY website to fill in the online questionnaire

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
182

Key exclusion criteria
Patients with a co-morbidity that negatively influences their cognition (for example dementia, stroke)

Date of first enrolment
26/06/2019

Date of final enrolment
31/12/2019

Locations

Countries of recruitment
United Kingdom

France

Germany

Italy

Netherlands

Study participating centre
Erasmus School of Health Policy & Management, Erasmus University Rotterdam
Bayle Building
Burgermeester Oudlaan 50
Rotterdam
Netherlands
3062 PA

Study participating centre
CIC Neurosciences, Institut de Cerveau et de la Moelle epiniere ICM
Hospital Petie-Salpetriere
47-83 bd de l'Hospital
Paris
France
75651 PARIS CEDEX 13

Sponsor information

Organisation
Erasmus School of Health Policy & Management

ROR
https://ror.org/057w15z03

Funder(s)

Funder type
Government

Funder Name
Horizon 2020 grant agreement No 720694.

Alternative Name(s)
EU Framework Programme for Research and Innovation, Horizon 2020 - Research and Innovation Framework Programme, European Union Framework Programme for Research and Innovation

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan
The trial data will only be used by the researchers within the same research field at the Erasmus University Rotterdam for patient confidentiality reasons. The research data be made available

(for example to check on scientific integrity) to a person outside the research group, only if truly necessary.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		20/03/2021	14/04/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes