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Benefit and risk information for medications in multiple sclerosis

Submission date
21/10/2016

Recruitment status
No longer recruiting

Registration date
26/10/2016

Overall study status
Completed

Last Edited
01/02/2021

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Multiple sclerosis is a condition affecting the brain and/or spinal cord that causes problems with vision, arm or leg movement, sensation and balance. Although multiple sclerosis can't currently be cured, there are medicines that can help to reduce the number and severity of relapses in some people, called disease-modifying medications. Patients with multiple sclerosis are faced with complicated information about the risks and benefits of disease-modifying medications. It is important that patients are able to understand and make decisions with confidence about these medications during consultations with health professionals. The aim of this study is to compare a new way of presenting risk and benefit information with the currently used presentation method. It is hoped that this will improve patients' understanding of the risks and benefits of medications and improve their confidence in their decision to choose a medication.

Who can participate?
Adult patients with relapsing-remitting multiple sclerosis (where patients have distinct attacks of symptoms which then fade away either partially or completely)

What does the study involve?
Participants are given the information about medication risks and benefits using the following four methods in a random order:
1. Currently used method, verbally
2. Currently used method, in a leaflet
3. New method, verbally
4. New method, in a leaflet
All medication information provided to participants is hypothetical but is similar to the risks and benefits of disease-modifying medications in multiple sclerosis. To measure their understanding, participants are asked a few questions about the information they receive. They are also asked to choose between the medications they are given and are asked a few questions about their confidence in their decision. Participants are also asked to complete a few questionnaires and tasks to measure their symptoms, characteristics and skills, to see how these factors may influence their understanding of information about medication risks and benefits.

What are the possible benefits and risks of participating?
The possible benefits are clearer presentation of risk-benefit information for medications, allowing for effective shared decision-making between patients and health professionals. Potential risks include questions requesting sensitive information, and causing psychological and physical discomfort such as fatigue since study sessions may last up to 2 hours. However, patients may omit any questions they do not wish to answer and are encouraged to take regular breaks when taking part in the study. Other similar studies have not encountered such problems.

Where is the study run from?
1. King's College Hospital NHS Foundation Trust (UK)
2. Lewisham and Greenwich NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
September 2014 to March 2017

Who is funding the study?
1. Biogen Idec (USA)
2. Royal Holloway, University of London (UK)

Who is the main contact?
1. Miss Gurpreet Reen (public)
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Contact information

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Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
GBR-MSG-13-10504

Study information

Scientific Title
Improving understanding and recall of risk information relating to multiple sclerosis medication - developing an evidence-based clinical tool for assisting communication and understanding of multiple sclerosis medication risk information between patients and health professionals

Acronym
Benefit and Risk information for Medication in Multiple Sclerosis (BRIMMS)

Study objectives
The evidence-based protocol will improve patients' decisional conflict and understanding of the risks and benefits of disease-modifying medications in multiple sclerosis, compared with information as usual.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Royal Holloway, University of London, 01/09/2016, ref: 2014/043
2. South Central Oxford C Research Ethics Committee, 23/09/2014, ref: 14/SC/1266

Study design
Interventional multicentre randomised crossover study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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

Interventions
The intervention in the study is the evidence-based protocol. This protocol will be used to provide information about medication risks and benefits from findings in the literature, and the observational studies that have been conducted by the authors.

The control in the study is information as usual. This involves providing information about medication risks and benefits using presentation methods used in current consultations.

Both the control condition and the intervention condition will be provided to patients verbally and in written format (leaflets) - thus, there will be a total of four conditions:

1. Consultation as usual provided in a verbal format (control verbal)
2. Consultation as usual provided with written information (control written)
3. Evidence-based protocol provided in a verbal format (intervention verbal)
4. Evidence-based protocol with written information (intervention written)

Patients in this study will be assigned to all four conditions in turn, but the allocation to the particular order of conditions will be randomised using a random number generator. All patients will be blinded to the conditions they receive.

All information provided during the study will be for hypothetical medications, but the risk and benefit information will closely mimic the current disease-modifying medications in multiple sclerosis.

Intervention Type
Behavioural

Primary outcome measure
Patients' decisional conflict, assessed using the Decisional Conflict Scale directly after each condition (i.e. four times in total)

Secondary outcome measures
Patients' understanding of the information provided during the study, assessed using an author-designed questionnaire directly after each condition (i.e. four times in total)

Overall study start date
01/09/2014

Completion date
01/03/2017

Eligibility

Key inclusion criteria
1. Diagnosis of relapsing-remitting multiple sclerosis (RRMS) by a consultant neurologist to best current criteria (i.e. not clinically isolated syndrome (CIS), likely Polman et al., 2011)
2. Able and willing to give informed consent
3. Able to meet tasks demands of study in terms of sensorimotor abilities
4. Ages 18 to 60

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
24

Total final enrolment
24

Key exclusion criteria
1. Significant change in medication in last 4 weeks
2. Relapse recovery within last 4 weeks
3. Significant psychiatric history/condition
4. Significant medical condition (other than MS), personal or social circumstances likely to influence study participation

Date of first enrolment
28/10/2016

Date of final enrolment
01/03/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

King's College Hospital NHS Foundation Trust
Denmark Hill
London
United Kingdom
SE5 9RS

Study participating centre
Lewisham and Greenwich NHS Foundation Trust
Stadium Road
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Sponsor type
University/education

ROR
https://ror.org/04g2vpn86

Funder(s)

Funder type
Industry

Funder Name
Biogen Idec

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Funder Name
Royal Holloway, University of London

Results and Publications

Publication and dissemination plan
It is expected that the findings form this study will be published in a peer-review scientific journal after the end of the project.

Intention to publish date
01/12/2017

Individual participant data (IPD) sharing plan
The current IPD sharing plans for the current study are unknown and will be available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	12/01/2021	01/02/2021	Yes	No
HRA research summary			28/06/2023	No	No