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A phase II baseline versus treatment study to determine the efficacy of raltegravir (ISENTRESS) in preventing progression of relapsing remitting multiple sclerosis as determined by gadolinium-enhanced MRI

Submission date	Recruitment status	[ ] Prospectively registered
22/08/2013	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
22/08/2013	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/08/2019	Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Miss Ailsa Weatherall

Contact details
Clinical Research Centre
Royal London Hospital
2 Newark Street
London
United Kingdom
E1 2AT
-
ailsa.weatherall@bartshealth.nhs.uk

Additional identifiers

EudraCT/CTIS number
2012-004847-61

IRAS number

ClinicalTrials.gov number
NCT01767701

Secondary identifying numbers
14731

Study information

Scientific Title
A phase II baseline versus treatment study to determine the efficacy of raltegravir (ISENTRESS) in preventing progression of relapsing remitting multiple sclerosis as determined by gadolinium-enhanced MRI

Acronym
INSPIRE: Raltegravir in Relapsing MS

Study objectives
This exploratory study will enrol patients with active MS lesions will be enrolled in a baseline versus treatment clinical trial where they will be observed for 3 months, having monthly Gd-enhanced brain MRI, blood, saliva and urine collection and neurological assessments and then treated with active open-label raltegravir (400mg twice daily) and followed up with monthly Gd-enhanced brain MRI, blood, saliva and urine collection and neurological assessments for a further for 3 months.

Ethics approval required
Old ethics approval format

Ethics approval(s)
12/EE/0544; First MREC approval date 10/01/2013

Study design
Non-randomised; Interventional; Design type: Not specified, Treatment

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Topic: Neurological; Subtopic: Neurological (all Subtopics); Disease: Nervous system disorders

Interventions
Raltegravir, open-label raltegravir 400mg twice daily; Follow Up Length: 6 month(s); Study Entry : Registration only

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Raltegravir

Primary outcome measure
Gadolinium enhanced MRI; Timepoint(s): MRI every 4 weeks from day 0 to day 168

Secondary outcome measures
Not provided at time of registration

Overall study start date
30/04/2013

Completion date
31/01/2014

Eligibility

Key inclusion criteria
1. Patients between 18-55 years of age.
2. Diagnosis of MS, according to the revised McDonald Criteria 2010.
3. EDSS score of 0-6.0 inclusive.
4. Documented at least one relapse within the past 12 months or at least one Gd-enhanced lesion on the brain MRI detected within 3 months prior to screening date.
5. Gd-enhanced lesion on screening MRI if MRI not used to meet screening criteria above.
6. Female patients of childbearing potential will be expected to be on appropriate contraception (hormonal or barrier method of birth control; abstinence) from time of consent until 6 weeks after treatment discontinuation. (the repeated administration of gadolinium and MRI are not recommended during pregnancy). NOTE: Subjects are considered not of child bearing potential if they are surgically sterile (they have undergone a hysterectomy, bilateral tubal ligation, or bilateral oophorectomy) or they are postmenopausal.
7. Females of childbearing potential must have a negative urine pregnancy test prior to every MRI scan/ within 7 days prior to being registered for protocol therapy.
8. Must give written informed consent and authorize the release and use of protected health information, as required by local law.
9. Able and willing to undergo blood, saliva and urine sampling at regular intervals as defined by the protocol.
10. Able and willing to receive Gadolinium enhanced MRIs at regular intervals as defined by the protocol.

11. Able to comply with study requirements.
Target Gender: Male & Female; Upper Age Limit 55 years ; Lower Age Limit 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
Both

Target number of participants
Planned Sample Size: 24; UK Sample Size: 24

Total final enrolment
31

Key exclusion criteria
1. Pregnant or breastfeeding or unwilling to use contraception.
2. Treatment with immunosuppressive, immunomodulatory or experimental treatments within the last 6 months of enrolment in the study, but excluding pulsed intravenous or oral steroids for treatment of MS relapse.
3. No pulsed intravenous or oral steroids in the 30 days preceding the baseline assessment.
4. Patients presenting with medical disorder deemed severe or unstable by the CI such as poorly controlled diabetes or arterial hypertension, severe cardiac insufficiency, unstable ischemic heart disease, abnormal liver function tests (>2.5 times ULN) and abnormal complete blood count (in particular leukopenia, as defined by a lymphocyte count <500, neutrophil <1.5 or platelet count < 100, or thrombocytopenia < 1.5 LLN), or any medical condition which, in the opinion of the chief investigator, would pose additional risk to the patient.
5. Presence of human immunodeficiency virus antibodies.
6. Patients receiving proton pump inhibitors (e.g. omeprazole/esomeprazole)
7. Patients with active hepatitis B or/and C with liver function tests >2.5 times ULN.
8. Exposure to any other investigational drug within 30 days of enrolment in the study.
9. Prior history of malignancy unless an exception is granted by the Chief Investigator.
10. History of uncontrolled drug or alcohol abuse within 6 months prior to enrolment into the study.
11. Patients treated with Rifampicin in past four weeks.

Date of first enrolment
30/04/2013

Date of final enrolment
31/01/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Clinical Research Centre
London
United Kingdom
E1 2AT

Sponsor information

Organisation
Queen Mary University of London (UK)

Sponsor details
R&D Office, Barts & London School of Medicine The QMI building
5 Walden Street
London
England
United Kingdom
E1 2EF

Sponsor type
University/education

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Industry

Funder Name
Merck Sharp & Dohme Ltd. (MSD) (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			21/06/2019	No	No
Basic results			19/08/2019	No	No
HRA research summary			28/06/2023	No	No