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AIMSPRO® and the bladder in multiple sclerosis (MS)

Submission date	Recruitment status	[X] Prospectively registered
07/10/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
24/10/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
17/07/2019	Nervous System Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01228396

Secondary identifying numbers
DIMS04

Study information

Scientific Title
A randomised, double-blind, placebo-controlled study of AIMSPRO® in secondary progressive multiple sclerosis (MS)

Study objectives
That AIMSPRO® will increase the average voided volume in patients with secondary progressive multiple sclerosis and overactive bladder symptoms.

More details on this trial can be found on the UK MS Society Clinical Trials Database at: http://www.mssociety.org.uk/research/clinical_trials/aimspro.html

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Committee, National Hospital for Neurology and Neurosurgery, University College London Hospitals Foundation NHS Trust

Study design
Treatment, parallel-assignment, double-blind (subject, caregiver, investigator, outcomes assessor), randomised, crossover, placebo-controlled, safety/efficacy trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Bladder dysfunction in patients with secondary progressive multiple sclerosis

Interventions
AIMSPRO® (manufactured by Sypharma Pty Ltd, Australia) vs placebo (cross-over trial).

1.0 ml twice weekly of AIMSPRO®/placebo for 4 weeks, injected subcutaneously, followed by a 6-week washout period and then the crossover medication for a further 4-week period.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
AIMSPRO®

Primary outcome measure
To determine whether the regular administration of AIMSPRO® improves bladder dysfunction, manifest as an increase in average voided volume

Secondary outcome measures
1. To determine whether the regular administration of AIMSPRO® improves other manifestations of bladder dysfunction including frequency, urgency and incontinence episodes
2. To determine whether regular administration of AIMSPRO® improves general disability
3. To verify findings from a peer-reviewed uncontrolled observational study related to possible changes in colour vision in MS patients taking AIMSPRO®

Overall study start date
01/11/2008

Completion date
01/03/2012

Eligibility

Key inclusion criteria
1. Male and female patients aged 18 years or older
2. Men and women of childbearing potential must use adequate birth control measures for the duration of the study and should continue such precautions for 6 months after receiving the last injection of AIMSPRO®
3. Clinically definite secondary progressive multiple sclerosis
4. Ambulant, walking aids allowed
5. No more than one relapse within the last 12 months and no relapse within the last 6 months
6. Urinary frequency of 8 times per 24 hours
7. Urinary urgency with or without urge incontinence
8. Magnetic resonance imaging (MRI) brain or spinal cord abnormalities consistent with the diagnosis of MS
9. Haemoglobin >9.5 g/dL
10. White blood cells (WBC) >3.5 x 10^9/L
11. Neutrophils >1.5 x 10^9/L
12. Platelets >100 x 10^9/L
13. Baseline AST, alkaline phosphatase, thyroid function, serum electrophoresis levels must be within their normal ranges
14. Able to adhere to the study visit schedule and other protocol requirements
15. Capable of giving written informed consent. Consent must be obtained prior to any screening procedures.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Acute symptomatic urinary infection
2. Taking DDAVP® for control of nocturia
3. Taking antimuscarinic agents for the control of overactive bladder symptoms
4. Full-time wheelchair user
5. History of immunosuppressant drug therapy of any kind in the last 3 months
6. Relapse within the last 6 months
7. No clear progression of disability in the last 12 months
8. Co-existent medical condition precluding participation, including any history of severe allergic reaction
9. Pregnant or lactating women and women who are planning pregnancy within 12 months of screening (i.e., approximately 6 months following last injection)
10. Receipt of any investigational drug within 30 days prior to screening or within 5 half-lives of the investigational agent, whichever is longer
11. Treatment with any therapeutic agent targeted at reducing tumour necrosis factor (TNF) (e. g., infliximab, pentoxifylline, thalidomide, etanercept, etc) within 3 months of screening
12. Previous administration of AIMSPRO®
13. Ongoing corticosteroid therapy or any corticosteroids within the previous 3 months
14. Known allergy to animal proteins
15. Known history of tuberculosis
16. Serious infections (such as pneumonia or pyelonephritis) in the previous 3 months. Less serious infections such as acute upper respiratory tract infection or simple urinary tract infection should be followed to their conclusion or treated, as appropriate, prior to inclusion
17. Opportunistic infections, including but not limited to evidence of active cytomegalovirus, active Pneumocystis carinii, Aspergillosis, histoplasmosis or atypical mycobacterium infection, etc, within the previous 6 months
18. Established malignant disease or renal, hepatic, haematologic, gastrointestinal, endocrine, pulmonary, or cardiac disease
19. A significant other neurological disorder
20. Presence of a transplanted organ, with the exception of a corneal transplant >3 months prior to screening
21. History of lymphoproliferative disease including lymphoma, or signs and symptoms suggestive of possible lymphoproliferative disease, such as lymphadenopathy of unusual size or location (such as nodes in the posterior triangle of the neck, infra-clavicular, epitrochlear, or periaortic areas), or splenomegaly
22. Known recent clinically significant substance abuse (drug or alcohol)
23. Poor tolerability of venepuncture or lack of adequate venous access for required blood sampling during the study period
24. Investigational drugs or drugs targeted at reducing TNF - these are not allowed during

participation in the study
25. Patients will not be permitted to receive immunosuppressive treatment during this study. The exception will be where a patient's treating neurologist determines that a course of steroid therapy, oral or intravenous, is required in view of a sufficiently disabling relapse of MS
26. Immunosuppressive therapy within the month prior to entry into the study
27. Taking the licensed anticonvulsant medication lamotrigine or the anti-arrhythmic drug flecainide, both of which are potent sodium channel blocking agents
28. Unable to fill in the criteria related to bladder dysfunction status
29. Unable to give written informed consent

Date of first enrolment
01/11/2008

Date of final enrolment
01/03/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London
London
United Kingdom
N19 5LW

Sponsor information

Organisation
Daval International Ltd (UK)

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Sponsor type
Industry

Website

http://www.davalinternational.com

ROR
https://ror.org/056p0fy66

Funder(s)

Funder type
Industry

Funder Name
Daval International Ltd (UK)

Results and Publications

Publication and dissemination plan
2016 results published in thesis: http://discovery.ucl.ac.uk/1474468/ (added 27/06/2019)

Intention to publish date

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

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