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Doxycycline And Rifampin for Alzheimer's Disease

Submission date	Recruitment status	[ ] Prospectively registered
06/10/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
06/10/2006	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/08/2020	Nervous System Diseases	

Plain English Summary
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MCT-79779

Study information

Scientific Title
Multi-centre, blinded, randomised, controlled trial comparing different regimens of the antibiotics Doxycycline and Rifampin for treatment of Alzheimer's Disease

Acronym
DARAD

Study hypothesis
Treatment with doxycycline and rifampin will slow or stop the progression of Alzheimers disease compared to those taking a placebo.

Primary objective:
To determine the impact of rifampin and doxycycline, over a one year period on cognition, function, mood, and behaviour.

Secondary objective:
To determine if treatment with either doxycycline or rifampin alone is as efficacious as the combined treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Research Ethics Board of Hamilton Health Sciences and McMaster University (Canada) on the 11th April 2006

Study design
Multi-centre, randomised factorial, four leg trial using placebo, with study participant, investigator, caregiver, outcome assessor and data analyst blinded.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Condition
Alzheimer's disease

Interventions

Experimental group 1: Doxycycline 100 mg twice daily (b.i.d.) plus placebo matched to rifampin 300 mg once daily (o.d.) for 12 months
Experimental group 2: Rifampin 300 mg o.d. plus placebo matched to doxycycline 100 mg b.i.d for 12 months
Experimental group 3: Doxycycline 100 mg b.i.d. for 12 months plus placebo matched to rifampin 300 mg o.d. for 12 months
Control group: Placebo matched to doxycycline containing microcrystalline cellulose 100 mg b.i.d. plus rifampin containing microcrystalline cellulose 300mg o.d. for 12 months

The public contact for this trial is:
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Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Doxycycline and rifampin

Primary outcome measure
1. Standardised Alzheimer's Disease Assessment Scale - Cognitive Subscale (SADAS-cog), measured at 12 months
2. Clinical Dementia Rating Scale (CDR), measured at 12 months

Secondary outcome measures
1. SMMSE, measured at 12 months
2. AB Cognitive Screen 100 (ABCS 100), measured at 12 months
3. Geriatric Depression Scale (GDS), measured at 12 months
4. Lawton Scale, measured at 12 months
5. Dysfunctional Behaviour Rating Instrument (DBRI), measured at 12 months

Overall study start date
01/05/2006

Overall study end date
30/11/2009

Eligibility

Participant inclusion criteria
1. Probable Alzheimer's disease
2. Aged 50 - 99 years old, either sex

3. Standardised Mini Mental State Examination (SMMSE) score 14 to 26 inclusive
4. Consenting patient (or Power of Attorney [POA] consents for patient)
5. Consenting caregiver
6. Sufficient English to complete standardised testing in English
7. May reasonably be expected to complete a one year trial

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
500

Participant exclusion criteria
1. Other neuro-degenerative diseases such as Lewy body, Parkinson's, fronto-temporal, Huntington's Chorea, Down's Syndrome or Creutzfeld Jacob Disease
2. Cognitive impairment due to acute cerebral trauma, subdural haematoma, injuries from chronic trauma, hypoxic cerebral damage
3. B12 deficiency, cancer or infections e.g. acquired immune deficiency syndrome (AIDS)
4. Endocrine deficiencies
5. Hypercalcemia, hypothyroidism, hyperparathyroidism, Cushing's syndrome, severe renal failure, poorly controlled diabetes mellitus, pituitary disease, etc.
6. Mental retardation
7. Significant cerebrovascular disease or multi-infarct dementia
8. Intra-cranial pathology, tumour or hydrocephalus
9. Co-existing medical conditions such as history of epilepsy or convulsions
10. Clinically significant psychiatric conditions or moderate to severe behavioural disturbances
11. Clinically significant hepatic, renal, pulmonary, metabolic or endocrine diseases
12. History of drug or alcohol abuse
13. History of myasthenia gravis
14. Clinically significant cardiac disease such as cardiac surgery in the past six months, unstable angina or poorly controlled congestive heart failure, uncontrolled hypertension with systolic pressure greater that 180 mmHg or diastolic pressure greater that 110 mmHg
15. Anti-dementia treatments except donepezil, galantamine, rivastigmine, memantine, acetylsalicylic acid (ASA) up to 650 mg OD, Vitamin E 400 i.u., multi B vitamins, Ginko biloba, Cyclooxygenase Type II (Cox II) inhibitors or statins
16. Other investigational drugs
17. Long-term antibiotics
18. Allergy to doxycycline or rifampin

Recruitment start date
01/05/2006

Recruitment end date
30/11/2009

Locations

Countries of recruitment
Canada

Study participating centre
St.Peter's Hospital
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Sponsor information

Organisation
McMaster University (Canada)

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Sponsor type
University/education

Website
http://www.mcmaster.ca/

ROR
https://ror.org/02fa3aq29

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-79779)

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?
Results article	results	01/05/2013		Yes	No
Results article	results	01/05/2019	19/08/2020	Yes	No