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Effect of trimetazidine MR 35 mg on the emergence of choroidal neovascularisation in age-related macular degeneration

Submission date 26/03/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/04/2009	**Overall study status** Completed	
Last Edited 18/04/2018	**Condition category** Eye Diseases	

Plain English summary of protocol
Not provided at time of registration and not expected to be available in the future

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MC3-06790-001

Study information

Scientific Title
Study of the effect of trimetazidine MR 35 mg (2 tabs/day) on the emergence of choroidal neovascularisation in age-related macular degeneration: a multicentre, randomised, double-blind, placebo-controlled, phase III study in 1100 patients treated for 3 to 5 years

Acronym
France DMLA 2

Study objectives
To demonstrate a difference between trimetazidine 35 mg and placebo on the emergence of choroidal neovascularisation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval was obtained before recruitment of the first participants

Study design
Randomised double-blind controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Aged-related macular degeneration

Interventions
Oral administration of trimetazidine 35 mg or placebo during 3 to 5 years.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Trimetazidine MR

Primary outcome measure
Effect on choroidal neovascularisation evaluated each year.

Secondary outcome measures
1. Effect of the serous drusen evaluated each year
2. Evaluation of pigment epithelium lesion evaluated each year
3. Clinical acceptability of trimetazidine evaluated each 6 months

Overall study start date
19/03/1999

Completion date
31/10/2005

Eligibility

Key inclusion criteria
1. Male and female
2. Caucasian
3. Aged 55 to 83 years with age-related macular degeneration
4. Neovascularisation on the first eye

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
1100 participants

Key exclusion criteria
1. Cataract
2. Diabetic retinopathy
3. Optical neuropathy
4. Neovascularisation on the studied eye

Date of first enrolment
19/03/1999

Date of final enrolment
31/10/2005

Locations

Countries of recruitment
Belgium

France

Spain

Study participating centre
Institution des Invalides
PARIS
France
75007

Sponsor information

Organisation
Institut de Recherches Internationales Servier (France)

Sponsor details
50 rue Carnot
Suresnes
France
92284

Sponsor type
Industry

Website
http://www.servier.com/

ROR
https://ror.org/034e7c066

Funder(s)

Funder type
Industry

Funder Name
Institut de Recherches Internationales Servier (France)

Results and Publications

Publication and dissemination plan
Summary results are published in https://clinicaltrials.servier.com.
For interventional Phase III studies ending after the 1st January 2014, the results are/will be published in scientific literature.

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from https://clinicaltrials.servier.com if a Marketing Authorisation has been granted after 1st January 2014.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results				No	No