

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/04/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/04/2018	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data

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

Contact name

Dr Christian Corbe

Contact details

Institution des Invalides
6 Boulevard des Invalides
Paris
France
75007

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