

Assessment of the effect of perindopril orodispersible tablet at the dose of 0.150 mg/kg /day on muscular and myocardic functions in the early stage of Duchenne Muscular Dystrophy: a two-year, double-blind, randomised, placebo-controlled study

Submission date 16/01/2009	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 16/02/2009	Overall study status Completed	☐ Protocol
Last Edited 21/04/2020	Condition category Nervous System Diseases	☐ Statistical analysis plan
		☒ Results
		☐ 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

Prof Isabelle Desguerre

Contact details

Groupe hospitalier Necker - Enfants Malades
149 rue de Sèvres
Paris Cedex 15
France
75743

Additional identifiers

Clinical Trials Information System (CTIS)

2008-003856-32

Protocol serial number

Study information

Scientific Title

Assessment of the effect of perindopril orodispersible tablet at the dose of 0.150 mg/kg/day on muscular and myocardic functions in the early stage of Duchenne Muscular Dystrophy: a two-year, double-blind, randomised, placebo-controlled study

Study objectives

Effect on peripheral muscular function.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval was obtained before recruitment of the first participants

Primary study design

Interventional

Study design

Double-blind randomised placebo-controlled study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Duchenne Muscular Dystrophy

Interventions

Perindopril orodispersible tablet 0.150 mg/kg/day versus placebo for two years.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Perindopril

Primary outcome(s)

Six-minute walking distance, evaluated each 6 months

Key secondary outcome(s)

1. Other muscular tests
2. Echocardiography
3. Respiratory function assessment

Evaluated at inclusion visit and end-of-study visit

Completion date

30/09/2012

Eligibility

Key inclusion criteria

Children, less than 7 years old with Duchenne Muscular Dystrophy and able to complete a 6-minute walk test

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Upper age limit

7 Years

Sex

Male

Total final enrolment

40

Key exclusion criteria

1. Long term treatment with corticoids
2. Treatment with ACE inhibitors or AT1 antagonists

Date of first enrolment

01/02/2009

Date of final enrolment

30/09/2012

Locations

Countries of recruitment

France

Study participating centre

Groupe hospitalier Necker - Enfants Malades
Paris Cedex 15
France
75743

Sponsor information

Organisation

Institut de Recherches Internationales Servier (France)

ROR

<https://ror.org/034e7c066>

Funder(s)

Funder type

Industry

Funder Name

Institut de Recherches Internationales Servier (France)

Results and Publications

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				No	No
Basic results			21/04/2020	No	No