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Fluvastatin in the therapy of acute coronary syndrome

Submission date	Recruitment status	[_] Prospectively registered
21/03/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/03/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/01/2020	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Petr Ostadal

Contact details
Dept. of Cardiology
University Hospital Motol
V Uvalu 84
Prague
Czech Republic
150 18

Additional identifiers

ClinicalTrials.gov (NCT)
NCT00171275

Protocol serial number
CXU0320BCZ01

Study information

Scientific Title
Fluvastatin in the therapy of acute coronary syndrome

Acronym
FACS

Study objectives
The primary objective of the FACS trial is to demonstrate that statin therapy, when started immediately after hospital admission for ACS, results in reduction of inflammation and improvement of prognosis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration.

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Acute coronary syndrome (ACS)

Interventions
Patients are randomized at admission to 80 mg fluvastatin (Lescol XL) or to placebo immediately orally (po) and then once daily for 30 days. Patients are followed up for 360 days.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Fluvastatin

Primary outcome(s)
Influence of fluvastatin therapy on levels of inflammatory markers (CRP and interleukin-6) and on pregnancy associated plasma protein A (PAPP-A)

Key secondary outcome(s)
A combined secondary endpoint is 30-day and one-year occurrence of death, nonfatal myocardial infarction, recurrent symptomatic ischemia, urgent revascularization, and cardiac arrest.

Completion date
01/01/2004

Eligibility

Key inclusion criteria
Eligible patients with ST elevation ACS must have resting chest pain less than 12 hours before admission and either >1 mm ST-segment elevation in 2 or more continuous leads or new left bundle branch block on electrocardiogram (ECG). Those with non-ST elevation ACS must have resting chest pain during the previous 48 hours and either >1 mm ST segment depression or negative T waves in 2 or more continuous leads.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/01/2003

Date of final enrolment
01/01/2004

Locations

Countries of recruitment
Czech Republic

Slovakia

Study participating centre
Dept. of Cardiology
Prague
Czech Republic
150 18

Sponsor information

Organisation
Novartis Pharma CR s.r.o.

ROR
https://ror.org/02f9zrr09

Funder(s)

Funder type
Government

Funder Name
Ministerstvo Zdravotnictví Ceské Republiky

Alternative Name(s)
Ministry of Health of the Czech Republic, MZCR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Czech Republic

Funder Name
Novartis

Alternative Name(s)
Novartis AG, Novartis International AG

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
Switzerland

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?
Results article	results	24/03/2005		Yes	No
Results article	results	25/05/2010		Yes	No