Main

Note: This record shows only 22 elements of the WHO Trial Registration Data Set. To view changes that have been made to the source record, or for additional information about this trial, click on the URL below to go to the source record in the primary register.

Register:	EUCTR
Last refreshed on:	2 February 2015
Main ID:	EUCTR2012-004406-10-CZ
Date of registration:	25/07/2013
Prospective Registration:	Yes
Primary sponsor:	University Hospital Hradec Kralove
Public title:	The use of oxygen-hydrogen mixture as an antioxidant
Scientific title:	The use of oxygen and hydrogen mixture for inhalation to prevent ischaemia-reperfusion injury - "Hydrogen"
Date of first enrolment:	09/10/2013
Target sample size:	
Recruitment status:	Authorised-recruitment may be ongoing or finished
URL:	https://www.clinicaltrialsregister.eu/ctr-search/search?query=eudract_number:2012-004406-10
Study type:	Interventional clinical trial of medicinal product
Study design:	Controlled: yes Randomised: no Open: yes Single blind: no Double blind: no Parallel group: yes Cross over: no Other: no If controlled, specify comparator, Other Medicinial Product: no Placebo: no Other: yes Other specify the comparator: Standard oxygen therapy (FiO2 40%) Number of treatment arms in the trial: 2
Phase:	

Countries of recruitment

Czech Republic

Contacts

Name:	Center for Research and Development	**Name:**	Center for Research and Development
Address:	Sokolska 581 500 05 Hradec Kralove Czech Republic	**Address:**	Sokolska 581 500 05 Hradec Kralove Czech Republic
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Affiliation:	University Hospital Hradec Kralove	**Affiliation:**	University Hospital Hradec Kralove

Key inclusion & exclusion criteria

Inclusion criteria:
The patients, aged 50-75 years (postmenopausal women only), suffering from acute myocardial infarction, transmural, originating from large vessel damage, will be included in the study. There cannot be any previous myocardial infarction, any previous cardiosurgery or cardiogenic shock present (Kyllip 1-3).
Are the trial subjects under 18? no
Number of subjects for this age range:
F.1.2 Adults (18-64 years) yes
F.1.2.1 Number of subjects for this age range 30
F.1.3 Elderly (>=65 years) yes
F.1.3.1 Number of subjects for this age range 30

Exclusion criteria:
Cardiogenic shock development, participation in another study, previus cardiosurgery, impossibility of primary PCI, diabetic decompensation, serious anamnestic nephropathy, serius anamnestic hepatopathy, cancer disease at present or previous five years, other serious comorbidities.

Age minimum:
Age maximum:
Gender:
Female: yes
Male: yes

Health Condition(s) or Problem(s) studied

Therapeutic area: Diseases [C] - Cardiovascular Diseases [C14]

The patients suffering form acute transmural myocardial infarction and treated with percutaneous transluminal coronary angioplasty will be included in the study. After the recanalisation of occluded artery, the reperfusion injury develops and the regeneration of ischemic tissue is impaired. The reactive oxygen species are partly responsible for reperfusion injury pathogenesis.

Intervention(s)

Product Name: Nitrogen-oxygen-hydrogen gas mixture (58%-40%-2%, respectively) for inhalation
Pharmaceutical Form: Medicinal gas, compressed
INN or Proposed INN: OXYGEN
Other descriptive name: oxygen gas
Concentration unit: % (V/V) percent volume/volume
Concentration type: equal
Concentration number: 40-

Primary Outcome(s)

Primary end point(s): The primary end-point is the effectivity evaluation of inhalational application of oxygen-hydrogen mixture against conventional oxygenotherapy on residual myocardial damage.

Timepoint(s) of evaluation of this end point: Visit 1: Patient iclusion into the study (day 0)
Visit 2: The end of coronary angioplasty (day 0)
Visit 3:Admission to ICU (day 0)

Visit 4: The morning of following day (day 1)Visit 5: The morning of following day (day 2)
Visit 6: The day of patient discharge.

Secondary Objective: Althouth there are not any available data regarding hydrogen toxicity and 2% concentration is low, the safety of oxygen - hydrogen mixture must be validated in the situation of acute coronary angioplasty.

Main Objective: Due to the fast growing body of information regarding positive effects of oxygen - hydrogen mixtures in various clinical conditions, it is necessary to evaluate its positive potential in the case of acute coronary angioplasty, where its fast diffusibility is especially profitable.

Secondary Outcome(s)

Timepoint(s) of evaluation of this end point: Visit 1: Patient iclusion into the study (day 0)
Visit 2: The end of coronary angioplasty (day 0)
Visit 3:Admission to ICU (day 0)
Visit 4: The morning of following day (day 1)Visit 5: The morning of following day (day 2)
Visit 6: The day of patient discharge.

Secondary end point(s): The secondary end-point is the safety evaluation of inhalational application of oxygen(40%) -hydrogen (2%) mixture during coronary angioplasty.

Secondary ID(s)

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Source(s) of Monetary Support

University Hospital Hradec Kralove

Secondary Sponsor(s)

Ethics review

Results

Results available:
Date Posted:
Date Completed:
URL: