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Circulating microparticles in obesity

Submission date
29/03/2015

Recruitment status
No longer recruiting

Registration date
26/04/2015

Overall study status
Completed

Last Edited
17/12/2020

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Obesity is a term used to describe somebody who is very overweight, with a lot of body fat. It's a common problem, estimated to affect around one in every four adults and around one in every five children aged 10 to 11 in the UK. People who are obese are at risk of a number of serious and potentially life-threatening conditions, such as disease of the heart or blood vessels (cardiovascular disease). Atherosclerosis is a serious condition where arteries become clogged up with fatty substances known as plaques. Plaques make the arteries harden and narrow, which restricts blood flow and can cause damage to organs by stopping them from working properly. They can also lead to blood clots which can trigger a stroke or heart attack. Atherosclerosis is the stage before cardiovascular disease, and it does not usually have symptoms until it is advanced and a person’s blood circulation is already restricted or blocked. When it is diagnosed at this late stage it is termed cardiovascular disease. There are a lot of studies looking into how diseases of the blood vessels can be diagnosed even earlier. A key process thought to be a precursor to atherosclerosis is endothelial dysfunction, which is an inflammation of the inner lining of the blood vessels. Endothelial dysfunction disrupts the normal functions of the blood vessels and is caused by various factors, such as smoking and being overweight. Endothelial function can be greatly improved by making lifestyle changes such as stopping smoking, exercising and losing weight. However, clinicians want to have an easy and accurate way of diagnosing endothelial dysfunction in patients early on. This will also allow them to advise patients of lifestyle changes that may be able to halt, or reverse, disease progression. Biomarkers (biological markers) are molecules that come from cells which can be found circulating in the blood. Scientists hope to use these biomarkers as a way of detecting changes in a person’s body at the very earliest stages of disease. The aim of this study is to investigate the content and structure of biomarkers called microparticles found in the blood of obese patients. The aim is to see whether these microparticles might be a reliable indicator of endothelial disease.

Who can participate?
Adults diagnosed as obese.

What does the study involve?
Participants have their body measured and blood samples taken. Various simple tests are used to determine cardiovascular function.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Sousse University (Tunisia)

When is the study starting and how long is it expected to run for?
December 2011 to December 2014

Who is funding the study?
Sousse University Hospital (Tunisia)

Who is the main contact?
Dr C Riva (scientific)
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
MIcroparticles in PAThophysiology of OBesity

Acronym

MIPATOB

Study objectives
Role of the microparticles in the pathophysiolgy of obesity

Ethics approval required
Old ethics approval format

Ethics approval(s)
Farhat Hached Hospital Ethical Committee for research on humans in Tunisia, 11/01/2011

Study design
Observational study single-centre

Primary study design
Observational

Secondary study design

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Domain of adult obesity

Interventions
1. Anthropometrics (body measurements)
2. Biological parameters and microvascular function (e.g. blood pressure, pulse rate)

Intervention Type
Other

Primary outcome measure
1. Microvascular assessment of cutaneous blood flow performed by the laser Doppler flowmetry technique at diagnosis and after exercise training
2. Plasma microparticules quantification and characterization by Flow cytometry at diagnosis and after exercise training

Secondary outcome measures
1. Circulating microparticles level
2. Informed written consent before inclusion

Overall study start date
01/12/2011

Completion date

30/12/2014

Eligibility

Key inclusion criteria
Adults with BMI ≥ 30kg/m²

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Total subject number = 410 (244 obese patients+166 control healthy subjects)

Key exclusion criteria
1. History of hypertension, antihypertensive medication or elevated sitting blood pressure (systolic blood pressure (SBP) ≥ 140 mmHg and/or diastolic blood pressure (DBP) ≥ 90 mmHg)
2. History of diabetes mellitus or fasting glucose > 7mmol/L
3. Any history or finding of cardiovascular disease, and/or undergone any cardiovascular procedures
4. Hyperlipidemia (total cholesterol > 6,7 mmol/L and/or triglycerides levels > 4,5 mmol/L)
5. Smoking
6. Consumption of any vasoactive medications or antioxidant supplements within the past 6 months

Date of first enrolment
01/12/2011

Date of final enrolment
30/12/2014

Locations

Countries of recruitment
Tunisia

Study participating centre
University of Sousse
Faculty of Medicine
Sousse
Tunisia
4002

Sponsor information

Organisation
Sousse University

Sponsor details
Faculty of Medicine
Sousse
Tunisia
4002

Sponsor type
University/education

ROR
https://ror.org/00dmpgj58

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Sousse University Hospital (Tunisia)

Funder Name
EA4278 Unit of the University of Avignon (France)

Results and Publications

Publication and dissemination plan

Intention to publish date

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	01/06/2016	17/12/2020	Yes	No