

Circulating microparticles in obesity

Submission date 29/03/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 26/04/2015	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 17/12/2020	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

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Additional identifiers

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

Study type(s)

Not Specified

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(s)

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

Key secondary outcome(s)

1. Circulating microparticules level
2. Informed written consent before inclusion

Completion date

30/12/2014

Eligibility

Key inclusion criteria

Adults with BMI $\geq 30\text{kg/m}^2$

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. History of hypertension, antihypertensive medication or elevated sitting blood pressure (systolic blood pressure (SBP) \geq 140 mmHg and/or diastolic blood pressure (DBP) \geq 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

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

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