The effect of the Ramadan fast on the weight status of obese adolescents

Published: 15-05-2012
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To observe the acute (at termination) and long-term (at 6 weeks after termination) effect of the Ramadan fast on body weight, glucose metabolism, lipid spectrum and body composition of obese adolescents.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational invasive

Summary

ID

NL-OMON37327

Source
ToetsingOnline

Brief title
Ramadan study

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Appetite and general nutritional disorders

Synonym
adiposity, obesity

Research involving
Human

Sponsors and support

Primary sponsor: Slotervaartziekenhuis
Source(s) of monetary or material Support: SKWOSZ

Intervention

Keyword: Obesity, Pediatrics, Ramadan, Weight

Outcome measures

Primary outcome

The main study endpoint is the effect of the Ramadan on changes in weight

status from baseline, measured as Z-BMI score.

Secondary outcome

Secondary endpoints are the effects of the Ramadan on glucose metabolism,

insulin resistance; serum levels of total, HDL- and LDL-cholesterol,

triglycerides, hs-CRP and body composition.

Study description

Background summary

The Ramadan fast is a month-long religious fast engaged by many Muslim families, including children and adolescents. Recent data in adults suggest that the Ramadan fast may result in weight loss and improved glucose and lipid levels of those who participate. However, contradicting results exist about the effect of the Ramadan fast on body composition. Thus far, this has not been studied in obese adolescents.

We hypothesize that the obese adolescents participating in the Ramadan will improve their weight status (expressed as a smaller standardised body mass index; Z-BMI score) and their metabolic profile, reflecting in a decrease of serum fasting glucose levels, serum LDL- and total-cholesterol and triglyceride levels, increase of HDL-cholesterol and improved body composition after the month of Ramadan fast.

Study objective

To observe the acute (at termination) and long-term (at 6 weeks after termination) effect of the Ramadan fast on body weight, glucose metabolism, lipid spectrum and body composition of obese adolescents.

Study design

Observational study of the effects on the weights status and metabolic profile of adolescents that participate in the Ramadan fast. Data on anthropometrics, glucose metabolism and lipid spectrum before the start, in the 4th week and 6 weeks after the Ramadan will be collected. Three 24h food diaries will be collected in the first, second and last week of the Ramadan. A calander will be used to determine how many days of the Ramadan where spent not fasting and/or abroad. The duration of the study will be approximately 13 weeks.

Study burden and risks

Considering the increasing rate of obesity and metabolic disturbances in youth, it is relevant to study the effects of the Ramadan fast on weight status and the metabolic profile in this population. The results may also aid pediatricians to give clinical advice about potential benefits and risks of participation in the Ramadan fast in the future. A calender and three 24 hour food diaries will be collected to gain insight in caloric intake and four visits to the Slotervaart Hospital for physical examination and blood sample drawing are needed. There are minimal risks involved and it is part of the standard work-up at the pediatric obesity outpatient clinic at the Slotervaart Hospital.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Paticipation in the Ramadan fast
- Age between 12-18 years
- Obesity as defined by Z-BMI score >2.3 (22)
- A written informed consent from participant as well as both parents (or guardian)

Exclusion criteria

- Obesity induced by underlying pathology, such as endocrine, a syndrome or chromosomal disorders, or chronic use of medication
- Pre-existing renal function disorder, diabetes mellitus or familial hypercholesterolemia
- Pregnancy
- Language barrier

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-06-2012
Enrollment:	45
Type:	Actual

Ethics review

Approved WMO Date:	15-05-2012
Application type:	First submission
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)
Approved WMO Date:	30-05-2012
Application type:	Amendment
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)
Approved WMO Date:	12-06-2012
Application type:	Amendment
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)
Approved WMO Date:	10-07-2012
Application type:	Amendment
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL40446.048.12

Study results

Date completed:	26-06-2013
Actual enrolment:	25