ISRCTN24376821 https://doi.org/10.1186/ISRCTN24376821

Pilot study on the effect of different dietary fatty acids on impaired glucose tolerance in obese urban Gambian women

Submission date	Recruitment status	[ ] Prospectively registered
23/10/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
03/01/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
03/12/2019	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Andrew Prentice

Contact details
MRC International Nutrition Group
Nutrition & Public Health Intervention Research Unit
London School of Hygiene & Tropical Medicine
Keppel Street
London
United Kingdom
WC1E 7HT
+44 (0)20 7958 8125
Andrew.Prentice@lshtm.ac.uk

Additional identifiers

Protocol serial number
Medical Research Council Gambia SCC Project # 854

Study information

Scientific Title
Pilot study on the effect of different dietary fatty acids on impaired glucose tolerance in obese urban Gambian women

Study objectives
Whether modifying the ratio n-3:n-6 polyunsaturated fatty acid dietary intake could prevent deterioration of impaired glucose tolerance in obese Gambian women.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was approved by the Gambia Government/MRC Joint Ethics Committee (Project # 816), approved March 2001.

Study design
Randomised double-blind control longitudinal intervention trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Obesity-related disease, non-insulin dependent diabetes mellitus

Interventions
Intervention group: High n-3 cooking oil (rapeseed oil) plus fish oil derived EPA/DHA capsules (3 g daily)
Control group: High n-6 cooking oil (sunflower oil) plus placebo corn oil capsules (3 g daily)

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
n-3 cooking oil (rapeseed oil), n-6 cooking oil (sunflower oil), fish oil derived EPA/DHA capsules.

Primary outcome(s)
Outcomes were measured before baseline, at baseline, at three and six months of the intervention:
1. Full plasma and adipose tissue fatty acid analysis
2. Fasting glucose
3. Fasting insulin
4. Oral glucose tolerance test

Key secondary outcome(s))

1. Anthropometric measurements (fat mass and fat free mass, waist-to-hip ratio)
2. Diastolic and systolic blood pressure
3. Full lipid profile
4. Plasma Tumour Necrosis Factor (TNF)alpha and receptors
5. Plasma InterLeukin-6 (IL-6) and receptors
6. Sialic acid

Completion date
08/05/2002

Eligibility

Key inclusion criteria
1. Female living in Bakau (urban area in the Gambia)
2. Aged 30 years or older
3. Being obese i.e. having a body mass index more than or equal to 27 kg/m^2
4. Having an impaired glucose tolerance (oral glucose tolerance test; 120-minute glucose between 6.7 and 10.0 mmol/l)
5. Subjects consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
Subjects diagnosed as diabetic by their doctor or on medication

Date of first enrolment
25/10/2001

Date of final enrolment
08/05/2002

Locations

Countries of recruitment
United Kingdom

England

Gambia

Study participating centre
MRC International Nutrition Group
London
United Kingdom
WC1E 7HT

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

ROR
https://ror.org/03x94j517

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Supplementary project grant to Gambia MRC Nutrition/NCD Programme

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration