Effect of IVF culture medium on health of IVF children

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

Summary

ID

NL-OMON44948

Source
ToetsingOnline

Brief title
MEDIUM-KIDS

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Lipid metabolism disorders
- Vascular hypertensive disorders

Synonym
growth and development, metabolic syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: March of Dimes

Intervention

Keyword: Children, Development, Health, IVF Culture Medium

Outcome measures

Primary outcome

The primary study parameters are blood pressure, heart rate, endothelial function (via iontophoresis and glycocalyx), lipid, TSH, HbA1c, insulin and glucose levels in blood, length, weight, waist and hip circumference and skin fold thickness and cortisol levels in hair.

Secondary outcome

DNA methylation in saliva.

Study description

Background summary

From animal studies it is known that embryo culture leads to growth, behavioral and cardio-metabolic alterations in the offspring. Embryo culture effects on human offspring have long been uninvestigated, until a few years ago when we found that the medium used to culture embryos in an IVF treatment has a significant effect on the incidence of low birth weight (LBW) and on birth weight. As this was the first randomized trial on embryo culture effects in human, nothing is known abouth health effects at later stages of development. Since a lower birth weight is related to an increased risk for (adult) chronic diseases belonging to metabolic syndrome (Barker theory), our findings raises concern for the IVF progeny. In advance of diseases at adult age, we hypothesize that IVF culture medium affects parameters of metabolic syndrome at childhood stage.

Study objective

The primary objective is to elucidate whether there is a difference in the outcome of health parameters between IVF children who as an embryo were cultured in two different culture media. As secondary objectives we will investigate how the health parameters of the IVF children (singletons) from the primary objective compare with those of non-IVF children and we will map

differences in DNA methylation profile between the children of the two culture media groups and between IVF and spontaneously conceived children.

Study design

In this observational study, all children born in our culture medium trial and spontaneously conceived control children will be called up for physiological (blood pressure, endothelial function (via iontophoresis and glycocalyx), stress response), metabolic (lipid profile, glucose), cognitive (Cito scores) and anthropometric (length, weight, skin fold thickness) examinations.

Study burden and risks

Consenting children from the IVF group and the IVF-siblings group (Control3), together with one or both parents, are asked to come to the MUMC (or a hospital closer to their home) once, for the following examinations: height, weight, skinfold thickness, blood pressure, endothelial function, lipid, glucose and insulin level in blood (3 sample of 5ml), cortisol level in hair and saliva collection (2ml) for DNA methylation analysis. The investigations will be performed by a researcher/physician under supervision of a qualified pediatrician. The investigations include regular medical examinations, which belong to *the risk of everyday life* that is seen as a negligible risk. The burden is reduced to a minimum by using anesthetic cream before the vena puncture (1 venapuncture of 15ml), and paying attention to resistance of the child. It is not possible to test our hypothesis in another (adult) study population since adult IVF progeny is scarce and since these IVF children are the first (worldwide) to be born after a randomized usage of two different culture media.
The parent(s) is/are asked to fill in a questionnaire regarding medical issues, lifestyle and demographic variables.
The anthropometric and physiological examinations in the children from Control 1 will be done at school. For control blood values we will use the surplus blood of children who had their blood samples taken for disorders that do not affect lipid profile like fractures or allergy Control 2.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

IVF group:
•born after an IVF treatment at the MUMC applied in the period July 2003 - December 2006
CONTROL 1 and 2:
•9 years old
•singleton
Control 3:
• 9 years old
• Singleton
• Have a brother or sister that belongs to the IVF group

Exclusion criteria

All:
• Mentally retarded defined as not able to understand the child information leaflet
IVF group:
• Born after preimplantation genetic diagnosis (PGD)
CONTROL 1 and 2 and 3:
• conceived by any form of assisted reproduction
CONTROL 2:
• having a disorder that affects lipid profile or glucose metabolism

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	26-03-2014
Enrollment:	245
Type:	Actual

Ethics review

Approved WMO Date:	19-02-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	16-01-2015
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	27-05-2015
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO	

Date:	17-09-2015
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	02-01-2017
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 27714
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL45845.068.13
Other	TC=4220
OMON	NL-OMON27714