Development Study in Youth with type 1 diabetes (DESTINY): Finding a balance Do the cognitive skills of adolescents with type 1 diabetes match their increasing responsibility for diabetes self management tasks?

Published: 19-12-2012
Last updated: 26-04-2024

The proposed longitudinal study aims to examine1) if the onset of type 1 diabetes before vs. during puberty results in different outcomes of glycaemic control, self management, psychological functioning and diabetes-related QoL2) how the development...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON39688

Source
ToetsingOnline

Brief title
DESTINY

Condition

- Other condition
- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Diabetes type 1, Juvenile diabetes

Health condition

psychologisch functioneren, cognitieve vaardigheden

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Diabetes Fonds en European Foundation of the Study of Diabetes (EFSD)

Intervention

Keyword: Children, Development, Puberty, Type 1 diabetes

Outcome measures

Primary outcome

Glycemic control (HbA1c) / Psychological functioning / Diabetes related Quality

of life and selfmanagement

Secondary outcome

Cognitive functioning / self esteem / autonomy / biological development

Study description

Background summary

Rationale: The DCCT/EDIC study has shown that strict glycaemic control during adolescence decreases the risk of developing complications later in life, even if this level of control is not maintained afterwards. However, the majority of adolescents with type 1 diabetes are in poor control and so far medical or psychological interventions have shown limited success. Adolescence is characterized by major biological, cognitive, psychological and social role changes and the complex interaction between these developmental trajectories, and its impact on health outcomes, is still poorly understood. A specific topic of interest in this context is the timing of diagnosis and how the cognitive development relates to self management skills.

Study objective

The proposed longitudinal study aims to examine
1) if the onset of type 1 diabetes before vs. during puberty results in different outcomes of glycaemic control, self management, psychological functioning and diabetes-related QoL
2) how the development of cognitive skills of adolescents with type 1 diabetes relates to their diabetes self management tasks and how this affects diabetes outcomes.

Study design

Longitudinal, observational study

Study burden and risks

To examine the psychological and cognitive development of children with diabetes throughout puberty, questionnaires and neuropsychological tests will be used. Children with diabetes are already accustomed to filling out questionnaires about their well-being in routine care. Completing the basic questionnaire within this study will take approximately 10 minutes and be done every 6 months for the 3 years of this study. We believe this won't be too much of a burden.
The neuropsychological tests and additional psychological questionnaires will take more time (appr. 3 hours) and could therefore be more of a burden. From previous experiences within our department, we know that children don't object to the tests and even like the 'games'. In this study, 4 tests will be assessed over the 3 years.
The physical measures (HbA1c, complication screening etc) are part of the routine care, no extra physical assessments are necessary for this research.

A selection of children will be interviewed about their eating behaviour. Time and place will be up to the children to minimize the burden.

Contacts

Public
Vrije Universiteit Medisch Centrum

Van der Boechorsstraat 7
Amsterdam 1081 BT
NL
Scientific
Vrije Universiteit Medisch Centrum

Van der Boechorsstraat 7
Amsterdam 1081 BT
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Type 1 diabetes, age 8-15 years

Exclusion criteria

Not fluent in Dutch and mental retardation

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2013
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	19-12-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-03-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL41105.029.12