Understanding adherence of adolescents with type 1 diabetes by measuring the daily tasks, bolus frequency and blood glucose levels.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Diabetic complications
Study type	Observational non invasive

Summary

ID

NL-OMON40035

Source
ToetsingOnline

Brief title
identifying adherence in adolescents with type 1 diabetes

Condition

- Diabetic complications

Synonym
diabetes type 1

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken

Source(s) of monetary or material Support: stichting WOKIK (wetenschappelijk onderzoek kindergeneeskunde isala klinieken).

Intervention

Keyword: adherence, adolescents, continuous subcutaneous insulin infusion, type 1 diabetes

Outcome measures

Primary outcome

Study the bolus frequency, the SMBG frequency, their interaction and influence

on hba1c value in a group of adolescents with diabetes type 1 during the two

months prior to a regular outpatient clinic visit

Secondary outcome

1. Is there a relationship between the SMBG-frequency and the bolus frequency.

2. Is one particular bolus most skipped (breakfast, lunch, dinner)

3. Is there a relationship between the SMBG-frequency and age.

4. Is there a relationship between the SMBG-frequency and diabetes duration.

5. Is there a relationship between the SMBG-frequency and gender.

6. Is there a relationship between the SMBG-frequency and the HbA1c.

7. Is there a relationship between the bolus frequency and age.

8. Is there a relationship between the bolus frequency and diabetes duration.

9. Is there a relationship between the bolus rate and gender.

10. Is there a relationship between the bolus frequency and HbA1c

11.What factors determine in particular the height of the Hba1c:

SMBG-frequency, bolus frequency, age, gender, diabetes duration, family

composition, level of education parents/adolescent, alcohol/smoking/drug use,

exercise?

12. what factors determine in particular the bolus frequency: SMBG-frequency, age, gender, diabetes duration, family composition, level of education parents/adolescent, alcohol/smoking/drug use, exercise?

13. what factors determine in particular the SMBG-frequency: bolus frequency, age, sex, duration of puberty, diabetes, educational level parents/adolescent, alcohol/smoking/drug use, exercise?

14. Is there a relationship between the use of the boluswizzard and the HbA1c levels.

15. Is there diabetes related stress by their parents and/or adolescent?

16. Is there diabetes related conflicts within the family?

17. How is the quality of life among our adolescents with diabetes?

Study description

Background summary

Adolescents often have trouble regulating their diabetes well. This concerns both the regular blood glucose measurements as the calculation and proper dosing of insulin bolusses. International studies so far show the cause for this poor adherence is multifactorial. . Psychosocial factors such as anxiety and depression, often occuring in adolescents with diabetes, relatively poor coping mechanisms and problem solving ability and hormonal changes during puberty may play a role. Optimal regulation is of great importance for the prevention of complications and early mortality. Furthermore reduction of complications will reduce health care costs. Until now there is no research done in the Netherlands, concerning adherence and its determinants in adolescents with diabetes. So it is unknown whether the factors that play a role in adherance in international studies also apply to adolescents with dm1 in the the Netherlands.

Study objective

The purpose of this observational study is to investigate the adherence during 2 months in adolescents with type 1 diabetes on subcutaneous insulin pump

therapy. The main outcome measure will be the amount of insulin bolusses and glucose measurements this will be compared with the "gold standard" (optimal diabetes management): at least 4 blood glucose measurements per day (i.e. for each meal and for the night). The ultimate goal is to examine what patient characteristics determine therapy adherence in adolescents with diabetes.

Study design

This is an observational study. During two months adherence in adolescents with diabetes type 1 is measured by the number of blood glucose measurements and mealtime insulin boluses given. Furthermore a questionnaire will be filled in to measure factors determining stress and quality of life .Based on these data , we want to design an intervention study with the aim to improve diabetic control by improving therapy adherence. This study is carried out at the Diabetes Centre Isala Clinics.

Study burden and risks

This study is conducted in children, because the study is aimed at improving diabetes care in children,This study does not include any risk for participating children and their parents and the load is minimal. The most important contribution of the participants is to once fill in some questionnaires taking maximum 1 hour. There is no risk for adverse serious events. Filling in the questionnaires will take less than 40 minutse.

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

Age 12 to 18 years.
Diabetes mellitus type 1, defined as, C-peptide levels <0.05 nmol / L at presentation and a glucose level> 7 mmol / L, positive autoantibodies, no evidence for MODY or type 2 diabetes.
>= 1 year type 1 diabetes.
>= 3 month subcutaneous insulin pump.

Exclusion criteria

mental retardation.
Inadequate knowledge of Dutch language.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending

Start date (anticipated):	01-01-2013
Enrollment:	80
Type:	Anticipated

Ethics review

Approved WMO Date:	25-02-2013
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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	NL41428.075.12