Iron status of children with diabetes type 1

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22325

Source
Nationaal Trial Register

Brief title
IRODIAB

Health condition

iron deficiency, children, diabetes type 1, HbA1c

Sponsors and support

Primary sponsor: Juliana Children's Hospital/Haga Hospital, the Hague, the Netherlands
Source(s) of monetary or material Support: Juliana Children's Hospital/Haga Hospital, the Hague, the Netherlands

Intervention

Outcome measures

Primary outcome

To assess the iron status of children with diabetes mellitus type 1, based on several iron status parameters.

ID will be classified according to the WHO criteria for ID (serum ferritin < 12 or < 15,

depending on the age).

Secondary outcome

- to identify determinants of ID & IDA in children with DM type 1.

- to investigate the influence of ID(A) on HbA1c levels.

Study description

Background summary

Rationale: Hemoglobin A1c (HbA1c) is the most reliable indicator of the average blood glucose concentration over a longer period of time in patients with diabetes mellitus (DM). HbA1c levels are influenced by factors that affect Hemoglobin (Hb) levels such as iron deficiency (ID). Higher mean HbA1c levels have been found in adults with either ID or iron deficiency anemia (IDA). ID and IDA occur more frequently among children. However the prevalence of ID and IDA among children with DM type 1 is unknown whereas information about the influence of the iron status on HbA1c in these children is scarce and incomplete.

Objective: To investigate the prevalence and determinants of ID and IDA in children with DM type 1. In addition, the relation between HbA1c and different iron status indicators will be determined.

Study design: A multi-center, cross sectional study.

Study population: 275 children with DM type 1, aged 1-18 years will be included in the study.
Intervention: According to the local regular health care standard, all children with DM type 1 undergo 3 monthly check-ups. In addition to blood sampling as part of the regular check-up, extra blood will be taken to evaluate the iron status (ferritin, reticulocyte hemoglobin content, transferrin saturation, hepcidin and zincprotoporphyrin). This requires 3 cc of extra blood. During the check-up, parents and patients will fill in a questionnaire about demographic characteristics, insulin use and dietary intake of iron.

Main study parameters/endpoints: ID will be classified when ferritin (SF) is < 12 µg/L in patients < 5 years of age and < 15 µg/L in patients > 5 years of age (WHO 2001). Metabolic

control will be classified by the amount of insulin used per kilogram per day. HbA1c >58 mmol/mol reflects chronic or frequently increased glucose levels during the previous 3 months.

Study objective

HbA1c is still considered to be the most reliable indicator of the average blood glucose concentration over a longer period of time and therefore used as a guide for treatment of patients with diabetes mellitus (DM). But, HbA1c levels are influenced by factors that affect Hemoglobin (Hb) levels such as iron deficiency (ID). Several studies have investigated the relationship between iron status and HbA1c levels in adults. The exact mechanism through which ID and IDA affect HbA1c levels is unclear, but it has been shown that ID and IDA are accompanied with higher mean HbA1c levels in adult patients and in pregnant women with and without DM type 1. There is also proof that iron repletion therapy results in lower HbA1c levels. Therefore it seems reasonable, when HbA1c is used as an indicator of blood glucose regulation in patients with DM type 1, that information about their iron status is taken into account. Information about the influence of the iron status on HbA1c in children with DM type 1 is scarce and incomplete.
So, in this study we will investigate the prevalence and determinants of ID and iron deficiency anemia (IDA) in children with DM type 1. We will also study the relation between HbA1c and ID/IDA.

Study design

One regular check-up moment at the ambulant clinic.

Intervention

No intervention.

Contacts

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Eligibility criteria

Inclusion criteria

- children, aged 1 to 18 years.

- diagnosis of DM for at least one year and based on internationally accepted definitions (Craig 2009).The period of one year is chosen to exclude children who are still in their honeymoon phase and who might use therefore less insulin.

- the need for the blood draw at the check-up moment

- written informed consent from parents/guardian and children themselves if >12 years.

Exclusion criteria

- known infections in the last four weeks

- C-reactive protein equal or above 5 mg/L

- oncologic disorder

- iron supplementation during the last six weeks

- blood transfusion during the last six months

- known hemoglobinopathies

- congenital malformations

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)

Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-07-2014
Enrollment:	275
Type:	Unknown

Ethics review

Positive opinion

Date:	10-06-2014
Application type:	First submission

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
NTR-new	NL4138
NTR-old	NTR4642
Other	: 14-016 METC

Study results