# Irostat.

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruitment stopped |
| **Health condition type** | - |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON22896

**Source**
NTR

**Brief title**
Irostat

**Health condition**

iron deficiency
iron deficiency anaemia
young healthy children from the Netherlands

### Sponsors and support

**Primary sponsor:** HAGA ziekenhuis / Juliana Kinderziekenhuis
**Source(s) of monetary or material Support:** HAGA ziekenhuis / Juliana Kinderziekenhuis

### Intervention

### Outcome measures

**Primary outcome**

1. Iron status;

2. Serum haemoglobin;

3. Mean cell volume and serum ferritin;

4. Reticulocyte hemoglobin content.

**Secondary outcome**

To define whether following factors contribute to iron deficiency during childhood:

1. Iron status at birth (maternal iron status/anaemia, smoking during pregnancy, preeclampsia, lower gestational age and lower birth weight);

2. Postnatal needs for iron (more rapid growth);

3. Bioavailable iron (more cow milk);

4. Sex;

5. Ethnicity (European versus non-European);

6. Socioeconomic status;

7. BMI;

8. Attending day-care.

# Study description

**Background summary**

Rationale:

No data are available about the iron status of children in the Netherlands. Recently a large food consumption survey showed low iron intake among these children. Our hypothesis is that the iron status in young healthy children from the Netherlands might be insufficient.

Objective:

To assess the iron status in young healthy children living in the Netherlands.

Study design:

National, multi centre, descriptive, observational study.

Study population:

Healthy children living in the Netherlands aged 0,5-3 years old undergoing elective surgery.

Intervention:

During insertion of a peripheral intraveneus catheter, 2 cc of whole blood will be collected for analysis of the iron status. Demographic, dietary and medical information will be collected.

Main study parameters/endpoints:

Serum haemoglobin, mean cell volume and serum ferritin and reticulocyte hemoglobin content.

13-02-2013: Additional information:
In the same blood sample obtained for assessment of the iron status we additionally assessed hepcidin and transferrin receptor to get more insight in the iron status.

### Study objective

Our hypothesis is that the iron status in young healthy children from the Netherlands might be insufficient.

### Study design

During insertion of a peripheral intraveneus catheter, 2 cc of whole blood will be collected for analysis of the iron status.

### Intervention

During insertion of a peripheral intraveneus catheter, 2 cc of whole blood will be collected for analysis of the iron status. Demographic, dietary and medical information will be collected.

## Contacts

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# Eligibility criteria

## Inclusion criteria

1. Male and female subjects, aged 6-36 months undergoing elective surgery;

2. General anesthaesia induced by intravenous injection;

3. Stable health status and expected to remain stable;

4. Written informed consent from parents/guardian.

## Exclusion criteria

1. Known infection in the last 4 weeks;

2. Oncologic disorder;

3. Acute or chronic illness;

4. Congenital malformations;

5. Chronic or inhereted metabolic disease;

6. Premature at birth (<32 weeks);

7. Hemoglobinopathies;

8. Use of iron supplementation less than 6 weeks prior to operation;

9. Blood transfusion in the last 6 months.

# Study design

## Design

| | |
|---|---|
| Study type: | Observational non invasive |
| Intervention model: | Factorial |
| Allocation: | Non controlled trial |

**Control:** N/A , unknown

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-01-2011 |
| Enrollment: | 400 |
| Type: | Actual |

## IPD sharing statement

**Plan to share IPD:** Undecided

# Ethics review

Positive opinion

| | |
|---|---|
| Date: | 02-12-2010 |
| 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 | NL2516 |
| NTR-old | NTR2634 |
| Other | METC : 2010-284 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

# Study results

**Summary results**
N/A