# Cognitive and motor development, nerve function, somatic growth and (pubertal) development, and (spontaneous) thyroid function in 10,5 years old Down syndrome children after thyroxine or placebo treatment until the age of 2 years.

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To find out whether T4 treatment of Down syndrome newborns until the age of 2 years compared with placebo treatment results in better cognitive or motor development at the age of 10 years and 6-8 months, and whether it is safe with regard to nerve…

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| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Chromosomal abnormalities, gene alterations and gene variants |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON33051

**Source**
ToetsingOnline

**Brief title**
Neurodevelopment in Down syndrome after thyroxine treatment early in life

### Condition

- Chromosomal abnormalities, gene alterations and gene variants
- Thyroid gland disorders

**Synonym**

"Down syndrome" en "Down's syndrome"

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum
**Source(s) of monetary or material Support:** Ministerie van OC&W,Farmaceutisc industrie: Ferring BV,Ferring

## Intervention

**Keyword:** Cognitive and motor development, Down syndrome, Thyroxine treatment

## Outcome measures

### Primary outcome

Cognitive development determined with the *Snijders-Oomen Non-Verbale Intelligentietest-Revisie* or with the mental scale of the Dutch second version of the *Bayley Scales of Infant Development* (BSID-II, in children with a severe delay).

### Secondary outcome

Gross Motor development determined with the *Movement Assessment Battery for Children* or with the psychomotor scale of the BSID-II (in children with a developmental age lower than 3 years). Fine Motor Development determined with the *Beery test of Visuo-Motor Integration*. Processing Speed measured with the baseline speed computer task of the *Amsterdamse Neuropsychologische Testbatterij*. Behavioural development determined with the *Vragenlijst omtrent ontwikkeling en gedrag bij kinderen*. Nerve function (conduction velocity) determined with a somatosensory evoked potentials test. Somatic growth and (pubertal) development determined with physical examination. (Spontaneous)

thyroid function determined with thyroid ultrasonography and laboratory tests.

# Study description

### Background summary

Thyroid hormone is indispensable for normal (pre- and) postnatal brain growth and development. As a group, young Down syndrome children have a mild form of (congenital) hypothyroidism that is not detected by neonatal screening and that may harm their brain development. To find out whether these children might benefit from thyroxine (T4) treatment, we conducted a randomized clinical trial comparing T4 and placebo treatment started in the neonatal period with cognitive and motor development at the age of 2 years as primary outcome (trial period: June 1999 to October 2003). In this trial we found that the T4 treated Down syndrome children had a smaller motor developmental age delay and, in a subgroup analysis, a smaller mental developmental age delay. Until now, data on the long-term efficacy (with regard to the development outcome) and safety of T4 treatment of Down syndrome children during their first 2 years of life are lacking.

### Study objective

To find out whether T4 treatment of Down syndrome newborns until the age of 2 years compared with placebo treatment results in better cognitive or motor development at the age of 10 years and 6-8 months, and whether it is safe with regard to nerve function, somatic growth and development, and (spontaneous) thyroid function at that age.

### Study design

Observational study.

### Study burden and risks

If the T4-treated Down syndrome children have a better developmental outcome at the age of 10 years and 6-8 months compared with the placebo-treated Down syndrome children, and the T4 treatment proves to be safe, it will be a strong argument in favour of adopting and implementing this treatment *standard care* for all (new) Down syndrome newborns. The risks of the current study are small and mainly concern pain associated with the blood collection and *discomfort* associated with the evoked potentials test. The pain will be minimized by the application of anaesthetic cream (Emla®) at the blood collection site. If the discomfort is too great, the sensory evoked potentials test will be ended and

skipped in accordance with the codes of conduct described in paragraph 7.3.

# Contacts

**Public**
Academisch Medisch Centrum

Postbus 22660
1100 DD Amsterdam
NL
**Scientific**
Academisch Medisch Centrum

Postbus 22660
1100 DD Amsterdam
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Children (2-11 years)

## Inclusion criteria

See item D3.

## Exclusion criteria

None

# Study design

## Design

**Study type:** Observational invasive

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

## Recruitment

NL

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| Recruitment status: | Pending |
| Start date (anticipated): | 15-11-2009 |
| Enrollment: | 181 |
| Type: | Anticipated |

# Ethics review

Approved WMO

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| Application type: | First submission |
| 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 | NL29139.018.09 |