# The (cost-)effectiveness of a new patient empowered protocol without routine x-rays for follow-up of adolescent idiopathic scoliosis patients; A pragmatic randomized trial

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To evaluate the (cost-)effectiveness of a new patient-empowered FU protocol in patients with AIS that is based on patient-reported outcome measures (PROMs), self-assessment tools and physical examination, which is compared to standard or usual FU...

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| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders) |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON54187

**Source**
ToetsingOnline

**Brief title**
CURVE

### Condition

- Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)

**Synonym**
adolescent idiopathic scoliosis, AIS

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Radboud Universiteit Nijmegen
**Source(s) of monetary or material Support:** ZonMw - ZorgEvaluatie & Gepast Gebruik

## Intervention

**Keyword:** adolescent idiopathic scoliosis, follow-up, patient empowerment, radiology

## Outcome measures

### Primary outcome

The proportion of x-rays that has led to treatment consequences for each

subgroup.

### Secondary outcome

(1) the proportion of patients with delayed initiation of (brace or operative)

treatment due to non-routine radiographic FU, (2) radiation exposure, (3) costs

from healthcare and societal perspective, (4) positive predictive value and

interrelation of clinical assessment, PROMs and radiological parameters for

initiation of treatment during FU.

# Study description

### Background summary

Adolescent idiopathic scoliosis (AIS) is a three-dimensional deformity of the spine and trunk that occurs during growth, which can result in life lasting consequences. The prevalence of AIS is 2-3% of initially healthy children and in the Netherlands each year 4-6,000 adolescents are newly diagnosed. Part of these children need bracing or surgical treatment to prevent progression of the curve and a negative effect on adult quality of life. Therefore, AIS patients are regularly seen in the outpatient clinic for radiological follow-up (FU) to detect curve progression, so that timely treatment can be initiated. After brace or surgical treatment, AIS patients are regularly seen at the outpatient department for radiological FU as well to detect any curve progression and/or surgical complications.

Current FU treatment protocols that are used as standard of care are based on a FU-range as recommended in national and international consensus meetings, but variation in follow-up frequency exists among Dutch scoliosis treatment centres. Regular performed consecutive full spine radiographs are standard care during FU for detection of progression or monitoring for complications after surgery. Routinely performed radiologic FU during the follow up leads to many x-rays without consequences for individual patient treatment, since spine curves are often not progressive. A recent study created awareness of exposing AIS patients to frequent radiographs by demonstrated and increased incidence of cancer in later life. The lack of evidence to support radiographic FU and possible harmful effects in children warrants investigation of new protocols in which x-rays are only acquired when curve progression or surgical complications are suspected.

The optimal frequency of radiological FU has not been studied and often radiographs are acquired that has not led to treatment. This means that most routinely obtained radiographs are without treatment consequences. An improved follow up protocol, including patient empowerment, is needed to decrease the number of radiographs without treatment consequences.

## Study objective

To evaluate the (cost-)effectiveness of a new patient-empowered FU protocol in patients with AIS that is based on patient-reported outcome measures (PROMs), self-assessment tools and physical examination, which is compared to standard or usual FU care.

This study is initiated by the Dutch Scoliosis Consortium, representing all scoliosis treatment centers in the Netherlands, and will result in an evidence-based guideline for follow-up of all adolescent patients (surgical, and non-surgical) with AIS.

## Study design

A multicenter pragmatic randomized trial design with two arms combined with a patient preference cohort for each arm (partially randomized preference trial [PRPT]).

## Intervention

The new patient-empowered and patient-based FU protocol is based on PROMs, self-assessment tools and clinical assessment including physical examination. The protocol aims to detect curve progression or postoperative complications based on these patient-based and clinical parameters to substitute the need to obtain routine x-rays. X-rays will only be taken when progression or postoperative complications are suspected in the pre- and post-intervention

groups based on predefined criteria. The standard FU protocol consists of routine full-spine radiographs and routine clinical evaluations.

**Study burden and risks**

AIS can be progressive during growth and detection by FU with consecutive radiographs is currently the standard of care. The potential benefit is that patients receive less ionizing radiation, as less radiographs are taken in the new patient empowered FU protocol. However, progression and/or post-operative complications may not be detectable until a later follow-up date, as routine radiographs will not be taken. Since the patient empowered FU protocol includes evaluation of PROMs and quantitative (self-)assessment tools during routine follow-up at the outpatient clinic, the risk of possibly missing potential serious progression of complications is minimized. Furthermore, routine radiographs at the end of the study period (at two year follow-up assessment) will be made to detect false negatives, which are radiological findings with treatment consequences (delayed bracing or operative treatment) that were not previously detected.

# Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

General
- Patients with AIS
- Age: 10-18 years old
- Patients scheduled for follow up in one of the participating centres
- Understanding of the Dutch language
- Signed informed consent
- Biplanar (Posterior-Anterior [PA] and Lateral) full-spine x-rays within the last 3 months

Specifically for the pre-treatment group:
- Girls aged <=14 years (i.e 10-14 years) and boys <16 years (i.e. 10-15 years).
- Girls: pre-menarche up to 6 months post-menarche (to estimate end of growth)
- A primary coronal curve of 10-25 degrees

Specifically for the post-brace group:
- Patients aged 12-18 years
- Within 3 months after termination of brace treatment
- Minimum of 6 months of brace treatment

Specifically for the post-surgery group:
• Patients aged 12-18 years

## Exclusion criteria

- Patients with juvenile or infantile idiopathic scoliosis with the diagnosis of onset under the age of 10.
- Patients who are undergoing brace treatment
- Patients who have undergone previous spinal surgery and are undergoing revision surgery.
- Skeletally mature patients.

# Study design

## Design

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| Study type: | Interventional |
| Intervention model: | Other |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Treatment |

## Recruitment

NL

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| Recruitment status: | Pending |
| Start date (anticipated): | 01-06-2021 |
| Enrollment: | 812 |
| Type: | Anticipated |

# Ethics review

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| Approved WMO Date: | 01-12-2021 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 04-04-2022 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 15-06-2022 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 19-07-2022 |
| Application type: | Amendment |

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| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 05-09-2022 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 07-09-2022 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 28-09-2022 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 02-01-2023 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 26-01-2023 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 05-09-2023 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |

# 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 | NL77456.091.21 |