# "Limited-efficay testing of spring distraction system (SDS) and a bilateral one way rod (NEMOST) for early onset neuromuscular scoliosis (BiPOWR)"

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Joint disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON50347

**Source**
ToetsingOnline

**Brief title**
BiPOWR study

### Condition

- Joint disorders
- Nervous system, skull and spine therapeutic procedures

**Synonym**
scoliosis, spine curve

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht
**Source(s) of monetary or material Support:** Euros ,Euros (France)

## Intervention

**Keyword:** Distraction system, Early Onset Scoliosis, Growth friendly system, Neuromusculair

## Outcome measures

### Primary outcome

Primary endpoints are the limited-efficacy in terms of maintenance of curve

correction and occurrence of SAEs related to the procedure.

### Secondary outcome

1) To assess the limited-efficacy in terms of length gain compared to our

previous cohort of MGCR patients and literature.

2) The randomised clinical trial design allows comparison of many outcomes

between the two systems

a) Amount of correction after surgery in terms of Cobb angle

b) Maintenance of the cobb angle after reduction

c) Spinal growth

d) Development of sagittal profile and instrumented thoracic kyphosis.

e) Surgical parameters like: surgery time, blood loss, length of hospital stay,

recovery time treatment related complications / reoperations

f) 3D correction based on (bone) MRI images and Ultrasound (Utrecht only).

g) Change in flexibility of the spine based on bending ultrasounds taken before

surgery, at 6 weeks and 6 months (UMC Utrecht only)

h) Patient overall appearance (shoulder balance and sagittal balance)

i) (Parent reported) QOL and performance with the EOS questionnaire

j) The effect on pulmonary function.

k) Effect on the development of the pelvic incidence (PI)

l) Performance in wheelchair

m) Postoperative length of the SDS and growth reservoir length of the NEMOST.

# Study description

### Background summary

Several innovative solutions have been developed to treat growing children with a severe scoliosis. One device (SDS) was developed internally at the department of orthopaedics UMC Utrecht in the Netherlands. The other device (NEMOST) was developed at the Necker Hospital in France.

### Study objective

The primary objective is to determine the limited-efficacy of both the experimental systems in comparison to our previous cohort that was treated with the more traditional MCGR. Limited-efficacy will be determined in terms of maintenance of the reduced curve after implantation of the system after one year.

### Study design

A feasibility study using two prospective cohorts according a randomised clinical trial.

### Intervention

Instead of the *standard treatment* (MCGR) one of the self-growing systems (SDS or NEMOST) is implanted according a randomized scheme.

### Study burden and risks

Burden: There is no extra burden with respect to the surgical procedure which is 2-4 hours and similar to the other growing rod procedures. As part of this

study patients and parents will be asked to visit the out-patient clinic one time more including an X-ray, fill in questionnaires (2 per visit about 10 mins), have three extra ultrasounds.

Risks: The biggest risk of these devices is that they do not maintain correction of the curve and/or do not grow as intended. . If spinal growth is insufficient a small re-operation is needed for manual distraction. This is similar to the standard bi-annual procedure in traditional growing rods.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

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

### Inclusion criteria

- Niet ambulant
- Neuromuscular or syndromal scoliosis
- Progressive scoliosis indicated for bipolar fixation extending to the pelvis

- Diagnosis of scoliosis before age 10
- Patient under 12 and open triradiate cartilage (usually closes around 12 years for girls and 14 years for boys)
- Main curve proximal end vertebra below Th 3
- Non rigid curve (at least 25% decrease on bending X rays)
- Patients who have an indication for a primary surgery

### Exclusion criteria

- Patients with closed triradiate cartilage
- Patients with a skeletal dysplasia that effects growth (Achondroplasia, SED)
- Patients with a systemic disease which severely influences bone quality e.g. osteogenesis imperfecta, metabolic diseases
- Patients with soft tissue weakness (Ehler Danlos, Marfan, Neurofibromatosis, Prader Willi)
- Patients that have a congenital anomaly of the spine of more than 5 vertebrae *
- Patients with an active systemic disease such as JIA, HIV, oncologic treatment
- Patients with a previous surgical fusion of the spine
- Patients that are expected to be lost to FU due to e.g. immigration within 2 years.
- Patients that have had a previous spine surgery.

## Study design

### Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Other |
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 06-05-2019 |
| Enrollment: | 28 |

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|---|---|
| Type: | Actual |

### Medical products/devices used

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| Generic name: | Necker Enfants Malade OSTeosynthesis (NEMOST) implant |
| Registration: | Yes - CE intended use |

## Ethics review

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|---|---|
| Approved WMO Date: | 20-11-2018 |
| Application type: | First submission |
| Review commission: | METC NedMec |
| Approved WMO Date: | 12-12-2018 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 24-04-2019 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 01-05-2019 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 21-06-2019 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 24-02-2020 |
| Application type: | Amendment |
| Review commission: | METC NedMec |

## 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 | NL64018.041.17 |
| Other | Wanneer het goedgekeurd is door de METC volgt hier het NCT nummer. |