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Bracing patients with adolescent idiopathic scoliosis: design of the first randomised controlled treatment trial

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Objectives

The effectiveness of bracing patients with adolescent idiopathic scoliosis (AIS) has not been convincingly established due to lack of Randomised Controlled Trials (RCT). The aim of this study is to evaluate whether bracing patients with AIS in an early stage will result in at least five degrees less mean progression of the curvature compared to the control group after two years of follow up.

Study design

Ten Dutch hospitals will participate in this (RCT). Eligible patients are girls and boys with AIS, aged eight to fifteen years old, who have not yet been treated by bracing or surgery and for whom further growth of physical height is still expected (Risser sign <3). The Cobb angle of the eligible patient should either be minimally twenty-two and maximally twenty-nine degrees with established progression of more than five degrees, or should be minimally thirty and maximally thirty-five degrees (established progression for the latter is not necessary). A total of 100 patients will be included in this trial. The intervention group will be treated with full-time Boston brace wear; the control group will not be braced. Every four months, a physical and an X-ray examination will take place for each patient.

Main outcomes

Cobb angle two years after inclusion and quality of life outcomes.

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