

Quality of life of adolescents with idiopathic scoliosis in Korea

Submission date 18/08/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 20/08/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 20/08/2015	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The spine is made up of a series of small bones called vertebrae. Scoliosis is a condition that causes the vertebrae to twist or rotate, causing the spine to curve sideways. There are several different types of scoliosis, however the most common type is known as “idiopathic”, which means that the exact cause is not known. Scoliosis can have a disfiguring effect on appearance. This is a particular problem in young people, who are often more concerned with the way their bodies look than adults, as it is a sensitive stage of development. It is thought that young people will experience a lot of emotional distress because of their condition, which can have an effect on their quality of life. This study aims to see how young people suffering from idiopathic scoliosis feel about their quality of life in relation to the disease characteristics and characteristics of the general population.

Who can participate?

Patients between the ages of 8 and 20 suffering from idiopathic scoliosis.

What does the study involve?

Participants are asked to fill in a questionnaire designed to find out how good they feel their quality of life is. The medical records of the participants are also reviewed by the researchers to collect information about how serious their disease is, the type of treatment they are having, and the age when the disease was first diagnosed.

What are the possible benefits and risks of participating?

There are no benefits of participating in the study other than providing new insight and valuable information of HRQoL of Korean adolescents with idiopathic scoliosis. There are no risks of participating.

Where is the study run from?

1. Severance Hospital (South Korea)
2. Kangnam Severance Hospital (South Korea)

When is the study starting and how long is it expected to run for?

November 2010 to August 2012

Who is funding the study?
Mo-Im Nursing Research Institute of Yonsei University (South Korea)

Who is the main contact?
Professor Jihea Choi

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Health-related quality of life of young adolescents conservatively treated for idiopathic scoliosis in Korea: a cross-sectional study

Study objectives
This cross-sectional study aims to describe and compare health-related quality of life (HRQoL) of adolescents with idiopathic scoliosis by disease-related characteristics such as age of diagnosis, type of treatment, severity of idiopathic scoliosis, as well as demographic characteristics.

Ethics approval required
Old ethics approval format

Ethics approval(s)

1. Institutional Review Board of Gangnam Severance Hospital: 24/11/2010, ref: 3-2010-0172
2. Clinical Trials Center (CTC) of Severance Hospital: 22/12/2011, ref: 4-2011-0682

Study design

Multi-centre observational cross-sectional study

Primary study design

Observational

Secondary study design

Cross sectional study

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet**Health condition(s) or problem(s) studied**

Scoliosis

Interventions

One hundred and ten adolescents with idiopathic scoliosis were recruited from two tertiary hospital outpatient clinics over 1 year. Health-related quality of life (HRQoL) of participants was measured using the Korean version of the Scoliosis Research Society 22 revision (SRS-22r) questionnaire. In addition, their medical records were reviewed to collect data on severity of scoliosis, type of treatment, and age at which they were first diagnosed with the disease.

Intervention Type**Primary outcome measure**

Health-related quality of life (HRQoL) is measured during clinical visits, measured using the Korean version of the Scoliosis Research Society 22 revision (SRS-22r) questionnaire. The SRS-22r contains 22 questions in five domains: function (5 items), pain (5 items), self-image (5 items), mental health (5 items), and satisfaction with management (2 items). Each item contains 5 response levels from worst (1 point) to best (5 point), and the results are expressed as the mean score of each domain and total score of the scale. A higher total score indicates a higher level of quality of life.

Secondary outcome measures

Not provided at time of registration.

Overall study start date

24/11/2010

Completion date

30/08/2012

Eligibility

Key inclusion criteria

1. Aged between 8 and 20 years
2. Having a primary diagnosis of idiopathic scoliosis.

Participant type(s)

Patient

Age group

Child

Lower age limit

8 Years

Upper age limit

20 Years

Sex

Both

Target number of participants

One hundred and ten adolescents with idiopathic scoliosis were recruited.

Key exclusion criteria

Any other diagnosable musculoskeletal disease, except for scoliosis and cognitive impairment.

Date of first enrolment

24/11/2010

Date of final enrolment

30/08/2012

Locations

Countries of recruitment

Korea, South

Study participating centre

Severance Hospital

Seoul

Korea, South

03722

Study participating centre

Kangnam Severance Hospital
Seoul
Korea, South
06273

Sponsor information

Organisation
Severance Hospital

Sponsor details
50-1 Yeonsei-Ro, Seodaemun-Gu
Seoul
Korea, South
03722

Sponsor type
Hospital/treatment centre

Organisation
KangNam Severance Hospital

Sponsor details
211 Eonju-Ro Gangnam-Gu
Seoul
Korea, South
06273

Sponsor type
Industry

Organisation
Severance Hospital

Sponsor details

Sponsor type
Not defined

Website
http://www.yuhs.or.kr/en/hospitals/severance/Sev_Intro/Gnr_info/

ROR

<https://ror.org/044kjp413>

Funder(s)

Funder type

University/education

Funder Name

Mo-Im Nursing Research Institute of Yonsei University (South Korea)

Results and Publications

Publication and dissemination plan

Intend to submit to the journal "Scoliosis" (<http://www.scoliosisjournal.com/>)

Intention to publish date

30/09/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request