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# Second opinion on spine surgeries: an option or necessity?

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 21/11/2012 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 25/02/2013 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 19/10/2017 | Signs and Symptoms | |

## Plain English summary of protocol

Background and study aims
Back pain is a very common symptom in adults. Whilst in most patients it tends to disappear either with conservative (non-surgical) treatment or spontaneously, there is a substantial group of patients who develop chronic (long-term) pain and need to undergo spine surgery. In the United States the estimated expenses related to people with spine complaints increased 65% from 1997 to 2005, faster than overall health expenditures.The aim of this study is to assess the effectiveness of a second opinion for patients who have been referred to undergo spinal surgeries.

Who can participate?
Patients aged 18 or older referred for spinal surgery for chronic back pain

What does the study involve?
Participants go to a private hospital in order to receive a second opinion on their surgery. They undergo examinations and are referred to undergo either non-surgical or surgical treatment. Participants allocated to non-surgical treatment undergo spine stabilisation (consisting of 20 physiotherapy sessions) and six sessions of acupuncture. When necessary, the participants are given the option of continuing the non-surgical treatment. If the treatment is not effective the participants can be referred to a spine surgeon. All participants are evaluated using telephone questionnaires at 1, 3, 6 and 12 months after the treatment to assess neck and low back pain, quality of life, and treatment side effects.

What are the possible benefits and risks of participating?
The possible benefits of participating in this study are participants can be assessed for a second opinion on their spine disease and can be treated in a spine centre. The risks of participating are those inherent to the treatment of spine problems (e.g. surgery infection, failure of treatment, need for surgery for patients allocated to a non-surgical treatment).

Where is the study run from?
Hospital Israelita Albert Einstein (Brazil)

When is the study starting and how long is it expected to run for?
May 2011 to May 2013

Who is funding the study?
Hospital Israelita Albert Einstein (Brazil)

Who is the main contact?
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# Contact information

### Type(s)
Scientific

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# Additional identifiers

### Protocol serial number
N/A

# Study information

### Scientific Title
Second opinion on spine surgeries: an option or necessity?

### Study objectives
The second opinion for patients who were indicated to undergo spinal surgeries is effective.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Plataforma Brasil, ref: 05736912.8.0000.0071

### Study design
Cohort study

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Symptoms related to diseases that affect the spine

## Interventions
Allocation
All patients covered by an insurance health company who received a surgical indication for their spine problems and who were included in the above criteria were referred to receive a second opinion appointment in a private hospital, for an assessment of their symptoms related to diseases that affect the spine. The initial patient approach was divided in three parts:
Firstly, a senior nurse provided them an overview of the spinal treatment program and explained how the second opinion works. She also collected all demographic characteristics of patients and gathered the primary and secondary outcomes.
Secondly, the patient was referred to two medical appointments; the first consultation was with a physiatrist and the second one was with a general orthopaedic surgeon. All appointments began with a thorough anammnesis, neurological and orthopaedic physical examination and a meticulous analysis of complementary exams brought to patients on the day of appointments (normally radiographic, resonance magnetic and electroneuromyography). Hereafter, the hypotheses and conclusions were reported to patients; when necessary, new or different subsidiary exams were requested.
Both appointments (by physiatrists and orthopaedics) were compared; achieving concordance between the diagnostic hypotheses and proposed of treatment, the patients were referred to two different paths of treatment: non-operative interventions or surgical treatment. Any disagreements were resolved by discussion and, when necessary, adjudication by multi-professional spinal board.
Finally, when conservative intervention was the choice of treatment, appointments were scheduled in a rehabilitation centre; when surgical treatment was option, the patient was referred to one of nine and senior spine surgeons (orthopaedic or neurosurgeon) having more than 15 years of spinal surgery experience.

Conservative intervention
All patients allocated to conservative intervention received a standard protocol of spine stabilisation (consisting with 20 physiotherapy sessions) and six sessions of acupuncture. When necessary, the patients were given the option of continuing the conservative treatment, all patients were seen in an out-patient office after each 10 physiotherapy appointments. When there was failure of conservative treatment, the patient could be referred to a spine surgeon of the program.

Surgical intervention
In all cases in which patients were designated to surgery, surgeons of a spinal board discussed possible techniques and the real necessity of a surgical intervention. Once a consensus for surgery was achieved, one of the nine surgeons of the board was randomly selected to perform it.

Outcome Assessment
Baseline data, which were collected by nurses not directly involved in the study, included sex,

age, height, weight, smoking status and alcohol use, medication use and primary indication to surgery prior to the second opinion. At baseline, each participant also was invited to fill quality of life and functional/disability questionnaires. All participants were evaluated by telephone questionnaires at 1, 3, 6 and 12 months after the treatment.
The primary endpoint was the score for overall neck and low back pain, measured on a visual analogical scale (VAS) of 0 to 10 (with 0 indicating no pain, 10 indicating the maximum pain) (Grotle 2004; Huskisson 1982). Secondary endpoint for neck and low back pain included health-related quality of life, measured by the Short Form-36 (Ware 1992); we also assessed function or disability endpoints for low back pain, measured by:
1. The RolandMorris Disability Questionnaire (Roland 1983; Roland 2000) validated and translated into Portuguese (Nusbaum 2001), in which scores range from 0 to 24, with higher numbers indicating worse physical functioning
2. Oswestry Disability Index (Fairbank 1980; Baker 1989; Roland 2000) the 2.0 version cross-culturally adapted to Brazilian Portuguese (Vigatto 2007); it includes 10 six-point scales, the sum of the 10 scores is expressed as a percentage of the maximum scores; the total of points ranges from 0 (no disability) to 100 (maximum disability).
We also reported all adverse events (complications) related with the conservative and the surgical treatments, they were assessed at each time point with the use of open-ended questions.

Data collected/reported
The data collected/reported in this paper were:
1. Baseline data (cited above)
2. First diagnosis hypothesis of first appointments (consensus between physiatrist and orthopaedic surgeons)
3. First indication for treatment by physiatrist and orthopaedic surgeons (referred patient to surgeon or conservative treatment)
4. When patients were referred to spine surgeon, data of each intervention were reported (conservative or surgery technique were also reported)
5. All outcomes above were assessed at first day, 1, 3, 6 and 12 months after the proposed treatment

## Intervention Type
Mixed

## Primary outcome(s)
Overall neck and low back pain, measured on a visual analogical scale (VAS) of 0 to 10 (with 0 indicating no pain, 10 indicating the maximum pain) (Grotle 2004; Huskisson 1982)

## Key secondary outcome(s))
1. Health-related quality of life, measured by the Short Form-36 (Ware 1992)
2. Function or disability endpoints for low back pain, measured by:
2.1. The Roland Morris Disability Questionnaire (Roland 1983; Roland 2000) validated and translated into Portuguese (Nusbaum 2001), in which scores range from 0 to 24, with higher numbers indicating worse physical functioning
2.2. Oswestry Disability Index (Fairbank 1980; Baker 1989; Roland 2000) the 2.0 version cross-culturally adapted to Brazilian Portuguese (Vigatto 2007); it includes 10 six-point scales, the sum of the 10 scores is expressed as a percentage of the maximum scores; the total of points ranges from 0 (no disability) to 100 (maximum disability).
3. Adverse events (complications) related with the conservative and the surgical treatments, assessed at each time point with the use of open-ended questions

Baseline data, which were collected by nurses not directly involved in the study, included sex, age, height, weight, smoking status and alcohol use, medication use and primary indication to surgery prior to the second opinion. At baseline, each participant also was invited to fill quality of life and functional/disability questionnaires. All participants were evaluated by telephone questionnaires at 1, 3, 6 and 12 months after the treatment.

### Completion date
01/05/2013

## Eligibility

### Key inclusion criteria
Recruitment of patients took place in a private hospital in order to give a second opinion of all patients who were referred to spinal (cervical and lumbar) surgical intervention from other hospitals. To be eligible, participants had to meet the following criteria:
1. Adults aged 18 years or older with any indication of spinal surgery due to lumbar or cervical stenosis, lumbar or cervical disc herniation, and other causes of chronic back pain including the annulus fibrosus of the disc, spinal ligaments, spinal nerves, dorsal root ganglia, zygapophyseal joint, sacroiliac joint, and paraspinal muscles
2. No medical contraindication to general anaesthesia
3. Understanding of Portuguese language and written informed consent

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Key exclusion criteria
1. Patients with spinal fractures
2. Scoliosis
3. Congenital spinal deformity
4. Spinal tumours
5. Inability to comply with follow-up (a transient or an inability to read or complete forms).

### Date of first enrolment
01/05/2011

### Date of final enrolment
01/05/2013

# Locations

### Countries of recruitment
Brazil

### Study participating centre
**Hospita Israelita Albert Einstein**
São Paulo
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05652-900

# Sponsor information

### Organisation
Hospita Israelita Albert Einstein (Brazil)

### ROR
https://ror.org/04cwrbc27

# Funder(s)

### Funder type
Hospital/treatment centre

### Funder Name
Hospital Israelita Albert Einstein (Brazil)

# Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not provided at time of registration

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 17/08/2017 | | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |