

Protocol Registration Receipt

12/06/2011

Watchful Waiting Versus Repair of Oligosymptomatic Incisional Hernias (AWARE)

This study is currently recruiting participants.

Verified by Johannes Lauscher, Charite University, Berlin, Germany, December 2011

Sponsor:	Charite University, Berlin, Germany
Collaborators:	German Research Foundation
Information provided by (Responsible Party):	Johannes Lauscher, Charite University, Berlin, Germany
ClinicalTrials.gov Identifier:	NCT01349400

► Purpose

Watchful waiting is non-inferior to surgical repair of asymptomatic and oligosymptomatic incisional hernias in terms of pain and discomfort during normal activities.

Condition	Intervention	Phase
Incisional Hernia	Watchful waiting Procedure/Surgery: Hernia repair	Phase 3

Study Type: Interventional

Study Design: Treatment, Parallel Assignment, Randomized

Official Title: Watchful Waiting vs. Repair of Oligosymptomatic Incisional Hernias

Further study details as provided by Johannes Lauscher, Charite University, Berlin, Germany:

Primary Outcome Measure:

- Pain/ discomfort during normal activities [Time Frame: 24 months]  
Pain/ discomfort during normal activities as a result of the hernia or hernia operation 2 years after enrolment measured by the hernia-specific Surgical Pain Scale (SPS) on a 150 mm-scale ranging from

“no pain sensation” to “most intense pain imaginable”.

Secondary Outcome Measures:

- Costs of treatment [Time Frame: 24 months]  
 Costs of treatment: direct costs(utilization of medical resources, purchase of drugs, costs of the operation, hospital stay) indirect costs: time off from work
- Patient satisfaction with care (5 point Likert scale) [Time Frame: 24 months]  
 Patient satisfaction with care is measured by standardized questions by 5 point Likert scale

Estimated Enrollment: 636

Study Start Date: November 2011

Estimated Study Completion Date: March 2017

Estimated Primary Completion Date: November 2016

Arms	Assigned Interventions
<p>Experimental: watchful waiting</p> <p>After informed consent and randomization into the watchful waiting group patients will receive standardized verbal information and written instructions on symptoms of acute incarceration. In case of acute symptoms they will be told to visit a physician immediately. On follow-up visits at 1 month, 12 months and 24 months the hernia size will be determined by physical examination, and the pain/ discomfort and the functional status will be monitored.</p> <p>Control intervention/ reference test:</p> <p>Open or laparoscopic hernia repair with mesh (non-absorbable or partly-absorbable alloplastic material) or with direct suture repair. For hernias measuring <math>\geq 3</math> cm mesh repair is recommended. A wide overlap of the mesh over the fascia margin on each side has to be provided. Divergent types of repair are permitted but have to be documented.</p>	<p>Watchful waiting</p> <p>Watchful waiting means the observation of the hernia. The patient is informed about signs of deterioration or incarceration. The hernia is controlled clinically on defined follow-up visits.</p>
<p>Active Comparator: Hernia repair</p> <p>Intervention: Open or laparoscopic hernia</p>	<p>Procedure/Surgery: Hernia repair</p> <p>Open or laparoscopic hernia repair with mesh</p>

Arms	Assigned Interventions
<p>repair with mesh (non-absorbable or partly-absorbable alloplastic material) or with direct suture repair. For hernias measuring <math>\geq 3</math> cm mesh repair is recommended. A wide overlap of the mesh over the fascia margin on each side has to be provided. Divergent types of repair are permitted but have to be documented.</p>	<p>(non-absorbable or partly-absorbable alloplastic material) or with direct suture repair. For hernias measuring <math>\geq 3</math> cm mesh repair is recommended. A wide overlap of the mesh over the fascia margin on each side has to be provided.</p> <p>These are all standard techniques in incisional hernia repair.</p>

Incisional hernias are one of the most frequent complications in abdominal surgery. In Germany, 44.000 incisional hernia repairs per year are performed. Incisional hernia repair is not a low risk operation associated with high recurrence rate and high percentage of postoperative pain. Treatment of incisional hernias represents a significant surgical and socioeconomic problem. Until now, surgical treatment is recommended for patients with incisional hernia independent of symptoms due to the risk of an acute incarceration with serious complications. Studies defining the exact indications for incisional hernia repair and describing the natural course of an incisional hernia including the risk of an acute incarceration are not available to date. Randomized controlled trials having been performed in the past few years show that observation is a reasonable option in mildly symptomatic inguinal hernias. In this study, watchful waiting vs. surgical repair of oligosymptomatic incisional hernias are compared in a prospective-randomized setting for the first time. The aim is to determine pain and discomfort, quality of life, patient satisfaction, and the frequency of incarceration. The investigators hypothesize that pain intensity during everyday activities is not different in the compared groups and that incarceration frequency is low. If this was the case, a watchful waiting strategy could be applied in oligosymptomatic incisional hernias and risks and costs for surgery could be saved.

## Eligibility

Ages Eligible for Study: 18 Years and older

Genders Eligible for Study: Both

Inclusion Criteria:

- age  $\geq 18$  years
- asymptomatic/ oligosymptomatic incisional hernia

Exclusion Criteria:

- no hernia detectable by physical examination
- acute incarcerated hernia
- emergency hernia repair
- pain or discomfort associated with the hernia during normal activities
- local or systemic infection
- ASA score  $>3$
- inability to complete or comprehend the preoperative questionnaire

- repair with biologic prosthesis

## Contacts and Locations

### Contacts

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### Locations

#### Germany

Charité Campus Benjamin Franklin    **Recruiting**

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Contact: Johannes C Lauscher, M. D.    0049 30 8445 Ext. 2542    johannes.lauscher@charite.de

Principal Investigator: Johannes C Lauscher, M. D.

### Investigators

Principal Investigator:    Johannes C Lauscher, M. D.    Charité Campus Benjamin  
Franklin, Berlin, Germany

## More Information

Responsible Party: Johannes Lauscher, Principal Investigator, Charite University,  
Berlin, Germany

Study ID Numbers: KS6-233

Health Authority: Ethics committee, Charité Berlin, Germany`