

A Multicenter, Prospective, Single-Blind, Randomized, Controlled, Study of the Repair of Challenging Abdominal Wall Defects: Strattice TM in abdominal Wall Repair (StaR)

Published: 10-01-2011

Last updated: 04-05-2024

The primary objective of this clinical study is to compare the incidence of post-repair wound related complications, including hernia occurrence/recurrence between challenging abdominal wall defects repaired with Strattice Reconstructive Tissue...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Abdominal hernias and other abdominal wall conditions
Study type	Interventional

Summary

ID

NL-OMON36351

Source

ToetsingOnline

Brief title

StAR

Condition

- Abdominal hernias and other abdominal wall conditions
- Skin and subcutaneous tissue therapeutic procedures

Synonym

abdominal wall defects, hernia

Research involving

Human

Sponsors and support

Primary sponsor: KCI Europe Holding B.V.

Source(s) of monetary or material Support: industrie

Intervention

Keyword: abdominall wall defect, hernia, pathologic processes, postoperative complications

Outcome measures

Primary outcome

Primary Endpoint: Hernia occurance at Month 12

Secondary outcome

Secondary Endpoints:

- Re-operation for abdominal wall repair within 12 months of repair
- Incidence of complications requiring intervention (medical or surgical), including occurrence of fascial dehiscence, wound infection and seroma, within the first 30 days after fascial repair,
- Length of hospital stay and resource utilization (eg OR time, days in speciality care)
- Mortality (all cause) at Day 30, Months 3, 6 and 12
- Resumption of Activities of Daily Living (ADL) as measured by the Activities

Assessment Scale, including return to work

Study description

Background summary

Synthetic absorbable and non-absorbable mesh materials are often used by surgeons to assist in the closure of abdominal wall defects. However, routine use of non-absorbable synthetic mesh in the setting of contamination can result

in chronic infection (which may require mesh removal), fistula formation, visceral adhesion, skin or visceral erosion, and mesh extrusion, while the use of absorbable polyglactin mesh has an expected 100% incidence of hernia occurrence. However, it is clear that most defects of any appreciable size should be repaired with a mesh to decrease the incidence of recurrence and other complications.

The literature has reported that biological mesh materials are successful in the use to repair abdominal wall defects; they are noted to be more tolerant of contaminated environments and even in the face of infection, may be treated in situ. In any case, in significantly contaminated or infected cases, steps should be taken to gain control of the infection, including, but not limited to, appropriate drainage, debridement, negative pressure therapy, and antimicrobial therapy prior and in addition to implantation of StratticeTM TM.

For post laparotomy fascial dehiscence, the clinical published literature has reported a variety of treatment modalities . Currently, the most common strategy for the management of fascial dehiscence is primary closure with suture. The literature indicates that this repair fails in 6 - 44%.

For the management of open abdomen or contaminated incisional hernia, the use of prosthetic mesh is still contraindicated under infectious or contaminated conditions, in which case a second stage repair should be considered, with or without using an absorbable mesh for acute management.

The literature reports significant evidence to suggest that a mesh should be used to repair abdominal defects of any appreciable size. Since these wounds are considered to be bacterial contaminated, the use of permanent synthetic mesh is contraindicated due to the high risk of local wound events and the potential for chronic infection. The use of absorbable (polyglactin) mesh has a higher initial success rate than primary suture closure in the management of abdominal wall defects, but almost always necessitates additional surgeries for repair of the abdominal wall.

The use of biological mesh in this setting where surgeons are hesitant to use synthetic meshes, to facilitate the repair of abdominal wall defects, will be investigated. In this post-market clinical study, the incidence of wound complications following repair decreasing post-repair morbidity, hospital stay, and mortality as well as the incidence of incisional hernia are being assessed.

Study objective

The primary objective of this clinical study is to compare the incidence of post-repair wound related complications, including hernia occurrence/recurrence between challenging abdominal wall defects repaired with Strattice Reconstructive Tissue Matrix undrelay and those managed by standard repair.

The secondary objectives of this study are to demonstrate the clinical utility of Strattice Reconstructive Tissue Matrix in the repair of abdominal wall defects.

Study design

This is a prospective, multicenter, single-blind, randomized, controlled study of the repair of challenging abdominal wall defects using Strattice Reconstructive Tissue Matrix or standard surgical repair.

Intervention

One group of patients will have their abdominal wall defect repaired with Strattice* TM, the other group of patients will have their abdominal wall defect repaired by the standard surgical practice of the hospital.

Study burden and risks

VISIT SCHEDULE

The participant will undergo surgery to close the abdominal wall. Before the surgery takes place, the participant's surgeon will ensure that there is no active infection present. If an infection is present, it may take a few days to treat the infection (for instance by antibiotic treatment, removal of dead tissue or other wound therapies) before surgery will take place.

During this period, the participant will undergo a standard physical examination and the medical and medication history will be reviewed and documented. Also, a photograph of the participant's abdominal wound will be taken. Only the participant's abdomen and wound will be in the photograph: nobody will be able to identify the participant from the picture taken.

On the day the participant's abdominal wall is ready to be repaired and surgically closed, he or she will be assigned randomly to one of the two treatment groups: one group of patients will have their wound repaired with reinforcement with Strattice* TM, the other group of patients will have their wound repaired by the standard surgical practice of the hospital.

The participant's assignment to a treatment group will be allocated by chance, like the flipping of a coin. He or she will have an equal chance of being assigned to either group. Neither the participant nor the investigator will know in advance to which group they will be assigned.

For the complete duration of the study, which is 12 months after the participant's surgery has taken place, he or she will not know in which treatment group they have been assigned. The reason for this is to exclude any unfairness when the participant is asked questions during their healing time

period.

Within 24 hours after assignment to a treatment group, the participant will undergo surgery to close her/his wound dehiscence. If the participant is assigned to the group in which Strattice* TM is used, the surgeon will place a piece of Strattice* TM under the the abdominal muscles during the participant's surgery to give it extra strength.

If the participant is assigned to the group in which current standard surgical practice will be applied, the wound will be either stitched closed with sutures alone, or reinforced with an absorbable mesh and then stitched closed. The surgeon will decide which of these treatments the participant will receive, depending on the size of the wound and other criteria.

Independent of the treatment group the participant is in, during the surgery, a small piece of tissue will be taken from the wound edge. That small piece of tissue (called a biopsy) will be no more than 1x1 cm in size and will be used to count the number and specify the type(s) of bacteria that might be present in the tissue. These results will provide information on the status of the wound immediately prior to closure.

The participant's tissue sample will only be used for the bacterial analysis and will be discarded after that analysis is complete.

After the surgery has taken place, the participant's doctor will follow up with the participant at several intervals during the course of one year:

At 7, 14 and 30 Days after the participant's wound dehiscence has been closed, the surgeon will evaluate the wound for any type of complications the participant may have or have had. During each of these appointments, a photograph of the participant's wound will be taken. At 30 days after surgery every participant will be asked to complete 2 short questionnaires on their status of daily activities.

At 3, 6 and 12 Months after the surgery for wound closure has taken place, the participant will be requested to visit the study surgeon again. During these visits, the surgeon will evaluate the wound for any complications and at each visit, a photograph will be taken. The participant will be asked to complete a short questionnaire regarding the status of daily activities. Every participant will also be asked when they have returned to work and whether or not they have been hospitalized. In addition to this, the participant will be asked regarding his or her satisfaction about the surgical repair procedure that was used.

If, at any time during the study, the surgeon suspects that the participant has a hernia, he or she will ask the participant to have a scan, either Magnetic Resonance Imaging (MRI) or Computed Tomography (CT), depending on standard hospital practice. These scans can confirm if the participant indeed has a hernia. The ordering of CT scans, when a surgeon suspects a hernia, will only be done if according to standard procedures within the participant's hospital

and if this CT scan would also have been ordered if the participant did not participate in this clinical study. In any other case, an MRI will be ordered. When the scan proves that a hernia has occurred, the study participant does no longer need to complete the remaining study visits, as the primary endpoint has been reached.

At 12 months after the surgery has taken place, the participant will be required to undergo an MRI scan of the abdominal wound site area. This scan will be performed in every case, even if the surgeon does not suspect that the participant has a hernia. This scan will allow the study surgeon to check if the participant has a hernia or not. All scans will be sent to a central reading facility, to have standardized, unbiased review and evaluation of all MRI scans.

If within 12 months following the initial repair of the fascial defect, a re-operation is deemed medically necessary (as per surgeon determination) to address a failure of the repair or to perform a planned final repair, such need will be identified and recorded. It is understood that multiple issues, both from the surgeon and the patient, may influence the decision as to whether or not a re-operation is actually undertaken. However, in the event that the re-operation is actually performed during the 12 month follow up period, in those patients who were randomized to and received a *standard repair*, they will be offered the use of Strattice* TM to support the repair. If Strattice* TM is used, these patients will be *crossed-over* into the Strattice* group and will continue to be followed for the balance of their participation in the study. If material(s) other than Strattice* TM is used to accomplish this new repair, those patients will have completed their participation in the study. For those patients who received Strattice* TM for the initial repair of their defect and for whom a re-operation is deemed medically necessary to address the failure of that repair (i.e. herniation), such necessity will be identified and recorded. Patients will continue to be followed until that repair is actually performed and will have completed their participation in the study at that time.

RISKS

The potential side-effects and risks of the surgical repair of an abdominal wall defect with Strattice TM or the standard of care treatment include:

- Those related to the surgery and anaesthesia, such as nausea, vomiting, headaches, bleeding, pain, abnormal clotting, infection and death;
- Those related to surgical and implantation techniques, such as seroma (collection of fluid between the layers of tissue in your abdominal wall), wound dehiscence (opening of the stitched wound), hematoma (a collection of blood between the layers of tissue in your abdominal wall), skin necrosis, (skin dying, usually at the edges of the wound) and cellulitis (a readness of the skin around the incision);
- Those related to the mesh, such as mesh tearing, rupture or stretching, and
- Those related to long term complications, such as infection and hernia

formation.

These risks are expected and considered acceptable for the surgical repair of a dehiscence abdominal wound with sutures or meshes.

There may be risks that are unknown at this time. Should any new developments arise and new information is known about potential risks of using Strattice TM in the course of this clinical study, we will inform the participant as soon as possible.

Any candidate will be warned in the information for consent to not participate in this trial if they are allergic to pork or sensitive to polysorbate

Additional burdens are:

- one additional MRI exam
- Tissue biopsy from wound edge. Although this will be done during surgery and patients are sedated and unconscious and therefore will not be considered a real burden
- possible additional post surgery follow up visits. Although some of those would also occur outside of the study.
- Completing questionnaires

Contacts

Public

KCI Europe Holding B.V.

Van Heuven Goedhartlaan 11
1181 LE Amstelveen
NL

Scientific

KCI Europe Holding B.V.

Van Heuven Goedhartlaan 11
1181 LE Amstelveen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- 1) Adult (= > 18 years old)
- 2) Written informed consent
- 3) Has need a surgical intervention of abdominal wall where:
 - a) The abdominal wall defect is considered to be (potentially) contaminated, but there is no manifest infection
 - b) Abdominal wall defect of a midline, transverse or Pfannenstiel incision
 - c) A significant abdominal wall defect of ≥ 3 cm and < 22 cm in length (along axis of incision), and
 - d) In case of open abdomen (skin and fascia open), the viscera have been exposed no longer than 15 days
 - e) Is willing and able to return for all scheduled and required study visits

Exclusion criteria

- 1) Has, at the time of Randomization (patient ready for abdominal wall closure)
 - a) severe systemic sepsis (demonstrable bacteremia and/or endotoxemia with hypo/hyperpyrexia, leukopenia/cytosis, tachypnea or hypocarbia, and/or tachycardia)
 - b) frank pus in the wound, a fistula that will not be closed at time of surgery or an intra-abdominal abscess in surgical area,
 - c) ongoing necrotizing pancreatitis, or
- 2) is on chronic immunosuppressive therapy, or other medication that influences wound healing
- 3) Requires only short-term closure (i.e. reentry is anticipated within the next week),
- 4) Requires a synthetic, non-absorbable mesh to close the abdominal wall defect
- 5) Is unable to undergo general anesthesia
- 6) Has serious medical risk factors involving any of the major organ systems such that the Investigator considers there to be serious risk of the subject not completing the study (e.g. AIDS or advanced cancer)
- 7) Is participating in another clinical study which may alter the postoperative healing response.
- 8) is unable to undergo an MRI scan (due to claustrophobia or other reasons)

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	29-04-2011
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	Strattice TM Reconstructive Tissue matrix
Registration:	Yes - CE intended use

Ethics review

Approved WMO	
Date:	10-01-2011
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO	
Date:	24-01-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO
Date: 27-04-2011
Application type: Amendment
Review commission: METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO
Date: 30-05-2011
Application type: Amendment
Review commission: METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO
Date: 14-11-2011
Application type: Amendment
Review commission: METC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)

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
ClinicalTrials.gov	NCT01083472
CCMO	NL32845.068.10