Clinical evaluation of the Articulinx Implant for the Carpometacarpal Joint.

Published: 10-11-2009
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To confirm the safety of the Articulinx implant by evaluating device and procedure related adverse events.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON35298

Source
ToetsingOnline

Brief title
Articulinx CMC study.

Condition

- Joint disorders

Synonym
Rizarthrosis, thumbarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Articulinx
Source(s) of monetary or material Support: Articulinx

Intervention

Keyword: arthroplasty, Articulinx, CMC, interpositional

Outcome measures

Primary outcome

Incidence of device and procedure related adverse events.

Secondary outcome

Average pain score post procedure compared to pre operative baseline.

Change in pain medication use (taken specifically for the hand) compared to

pre operative baseline.

Change in joint function post procedure compared to pre operative baseline.

Study description

Background summary

A clinical need exists for an early treatment of osteoarthritis of the hand that mitigates pain and restores biomechanics without drugs or radical surgery. Articulinx Inc. has developed an alternative treatment for Osteoarthritis of the hand. The implant is designed to be inserted into the CMC joint of the hand, restoring the space between the the joint surfaces without disrupting joint architechture or removing supporting bone or soft tissues. A simple minimally invasive procedure is required to insert the implant. The Articulinx implant is designed to be implanted earlier in the disease process, allowing a more active lifestyle and potentially reducing or eliminating the need for long term use of prescription medications.

Study objective

To confirm the safety of the Articulinx implant by evaluating device and procedure related adverse events.

Study design

A non randomised, prospective, non controlled study.

Intervention

Minimally invasive surgical procedure.

Study burden and risks

Not applicable.

Contacts

Public
Articulinx

1601 S. De Anza Blvd., Suite 215
CA 95014, Cupertino
US
Scientific
Articulinx

1601 S. De Anza Blvd., Suite 215
CA 95014, Cupertino
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Adults between ages 40-75 with stage I or II osteoarthritis (according to Eaton Littler classification) of the CMC I joint. Subluxation less than 1/3 of the joint. Patients who are capable of providing informed consent and willing to adhere to the follow up schedule.

Exclusion criteria

Significant and affecting pathology of the radial side of the hand and wrist.
Significant osteophytes of the CMC I joint.
Metabolic disorders of the bone.
Prior surgery that precludes placement.
Participating in another study.
Pregnancy and lactation.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-11-2009
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Articulinx Implant for the CMC I joint.
Registration:	No

Ethics review

Approved WMO

Date:	10-11-2009
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO Date:	13-12-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
CCMO	NL28895.029.09