The Implant Removal Trial

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Implant removal has no effect on the pre-operative complaints of the patient like pain, stiffness, functional problems and/or daily problems.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27207

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

implant, removal, hardware, osteosynthesis, refracture, plates, nails, complications

verwijderen osteosynthese, platen, pennen, refractuur, complicaties

Ondersteuning

Primaire sponsor: fund = initiator = sponser
Overige ondersteuning: fund = initiator = sponser

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Is the pre-operative suspected result of the operation being achieved?

Toelichting onderzoek

Achtergrond van het onderzoek

In the Netherlands each year about 18.000 times operations are carried out to remove metal implants. The indication for removing this material is not always well defined. The Arbeidsgemeinschaft fur Osteosynthesefragen (the AO) used to advise to remove all the materials. The reason for this was the supposed risk for corrosion and loosening of metal parts.
But routinely removing osteosynthetic implants has some disadvantages. The operation itself can be difficult to perform and there is a realistic chance for complications, general complications, but also specific operation related complications, like the risk for nerve damage and the risk for a refracture, small scars can become bigger and patients without complaints previous to the operation can get complaints after the operation. All these complications are frequently described in literature, uptill 40%, depending on the experience level of the surgeon. Apart from the operation risk's, each intervention has it's own recovery period and employment loss with social consequences and costs.

Most studies about the removing metal implants are from a older data and generally discus about metal implants made of iron, chroom, nickel and molybdenum. There is less known about the indications of removing the more modern materials made of titanium. Complications hereby are just described in some case reports.

The indications for implant removal can be divide into two groups. There are absolute and relative indications. For example material which is perforating the skin, like an external fixator, should always be removed. Also growing bone and infections of the bone still are absolute indications, though in literature there is some discussion about this.
A relative indication for implant removal is for example the argument that in the lower extremity the material can give a problem in future when a hip or knee replacement should be done. Rather important relative indications are complaints of the patient about pain, swelling and stiffness without that it is clear that the material is the underlying cause of this, like in intramedullairy nails. There also are functional and/or cosmetically "disturbing" implants, mostly lying just under the skin like the clavicle plate or at the olecranon.
Often the material is being removed because of the patient is asking as precaution e.g. with sporting or because somebody told him to do so. The question is whether removing metal implants is a useful operation in this group of patients.

Up till now no prospective studies are undertaken to look for the best strategy whether to remove or not to remove osteosynthesis.

AIM OF THE STUDY

This study aims to investigate all the medical, historical, psychological and other indications for implant removal.
Also the per- and post-operative complications related to this operation shall be registered. We'll look at in which way the pre-operative expected results are being obtained when it comes to complaints and restrictions. Also the costs of the operation and the social consequences shall be looked at.

Ultimately we hope to have structured arguments that should contribute to a consensus and guidelines for the indication of implant removal.

METHODS

A prospective, multicentre, clinical cohort study will be done. All adult patients with a healed fracture, clinically and radiologically, of the clavicle, radius, ulna, femur or tibia, after nail- or plate implantation, for which there is a relative indication for implant removal will be included. This 'relative indication' means complaints of the patient like pain, stiffness, swelling of the operated limb, without sings of infection. Using a pre-operative list all the indications and complaints of the patient shall be recorded. The follow up after removal of a nail shall be 6 month and after removal of a plate one year. During this follow up complications will be recorded like re-bleeding, wound infection, nerve damage and re-fracture. The complaints and the satisfactory of the surgeon will be scored (at 2 weeks, 6 weeks, 6 months and / or one year). Also x-rays shall be made on standard times (pre-operatively, 2 weeks, 6 months and one year (only in plate removal) post-operatively).

After the indication for implant removal has been made the possibility of participation in the study will be discussed with the patient. He or she has to fill in the informed consent and after this permission the patient has to fill in a pre-operative list, one after 6 weeks and one after 6 months and one year (only in plate removal). These questionnaires quantitate pre- and post-operative symptoms and problems that can lead to the operation indication. Approve for this study has been gained by the medical ethical commission.

Doel van het onderzoek

Implant removal has no effect on the pre-operative complaints of the patient like pain, stiffness, functional problems and/or daily problems.

Onderzoeksopzet

The patient and surgeons questionarry needs to be filled in pre-operatively, during the operation, after 2 weeks, after 6 weeks, after 6 months and when a plate has being removed also after a year.

This means a follow up from half a year after nail removal and a year after plate removal.

Onderzoeksproduct en/of interventie

The operation in which the osteosynthesis is being removed takes place in the same manner as usual under local or general anesthesia. The one who operates is an orthopedic or general surgeon or a resident (junior or senior). The surgeon makes up wether the C-arm has to be used, the use of antibiotics, bloodspareness and/or venous tromboembolism prophylaxis has to be used. Also the surgeon decides how the post-operative care, like immobilisation, restarting work or sports, has to be done. Postoperative pain is being treated according to the local protocol for analgesia.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. All patients of 18 years and older who have an osteosynthesis (plate or nail) of their clavicle, radius, ulna, femur or tibia and who are planned for an implant removal.

2. The fracture needs to be healed (consolidation) clinically and on radiology.

3. The patient has to give permission by a signed informed consent form.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. All patients younger than 18 years.

2. Patients who had an other trauma in their previous history of the same extremity, through which the already had a limitation of mobility, pain and/or stiffnes which could explain their complaints (when supposed that the complaints of the patient are possibily caused by the osteosynthesis material than the patient can be included for the trial.

3. Non consolidated fractures, other osteosynthesis material and/or implanted in other than the mentioned bone.

4. No informed consent.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2007
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	25-04-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 33611
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1251
NTR-old	NTR1297
CCMO	NL15133.008.07
ISRCTN	ISRCTN wordt niet meer aangevraagd
OMON	NL-OMON33611

Resultaten

Samenvatting resultaten
N/A