Gentamicin serum levels with gentamicin impregnated PMMA-beads

Published: 02-02-2009
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Objective: To study the frequency of measurable gentamicin serum levels in patients with gentamicin PMMA-beads in situ.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON35413

Source
ToetsingOnline

Brief title
Gentamicin serum levels with gentamicin impregnated PMMA-beads

Condition

- Bacterial infectious disorders
- Joint disorders
- Bone and joint therapeutic procedures

Synonym
gentamicin serumlevels

Research involving
Human

Sponsors and support

Primary sponsor: ziekenhuisapotheek
Source(s) of monetary or material Support: wetenschapsfonds MMC;onderzoeksbudget ziekenhuisapotheek MMC

Intervention

Keyword: gentamicin, PMMA, serumlevels

Outcome measures

Primary outcome

Main study parameters/endpoints: Gentamicin serum level > 0,4 mg/l

Secondary outcome

• To determine specific patient groups at risk of developing gentamicin serum levels > 0.4 mg/l after implantation of gentamicin PMMA-beads.

• To investigate the height of gentamicin serum levels after implantation of gentamicin PMMA-beads.

• To investigate the duration of raised gentamicin serum levels > 0.4 mg/l.

• To investigate the occurrence of nephrotoxicity or other toxicities due to gentamicin PMMA-beads.

• To relate the gentamicin serum level to the number of implanted beads

• Gentamicin serum level > 0.02 mg/l, measured with a modified TDxFLx method

Study description

Background summary

Rationale: According to the Septopal® (gentamicin PMMA-beads) SPC toxic side-effects are not to be expected due tot the limited amount of systemically available gentamicin. However, two recent cases have demonstrated that raised gentamicin serum levels can indeed be detectable for a longer period of time after implantation, which can lead to toxic side-effects. In this study we try to obtain systemic gentamicin levels for every patient with newly implanted gentamicin PMMA-beads in order to determine the frequency of measurable serum levels.

Study objective

Objective: To study the frequency of measurable gentamicin serum levels in patients with gentamicin PMMA-beads in situ.

Study design

Study design: Observational, prospective pharmacokinetic study

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The burden for patients is the limited extra amount of blood (maximum 30 ml) taken for measurement of gentamicin serum levels during routine blood takings. Maximally 3 blood takings per patient are required in this study.

Contacts

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Selecteer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Orthopedic patients who will have gentamicin PMMA-beads implanted

Exclusion criteria

• Administration of gentamicin in any other way then implantation of gentamicin PMMA-beads seven days prior to the first taking of gentamicin serum level up to taking of the final gentamicin serum level for this study.
• Legally incapable patients
• Patients under the age of 18 years old
- Breastfeeding women
- Pregnant women
- Allergy to aminoglycosides

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-03-2009
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	03-02-2009
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	11-01-2010
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	09-03-2010
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	20-04-2010
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL25363.015.08