

Study protocol

Implementation of a new antibiotic prophylaxis for percutaneous endoscopic gastrostomy (PEG) in Sweden.

Background

In year 2010 we published a randomised clinical trial in BMJ testing a new antibiotic prophylaxis regimen to prevent infectious complications after insertion of PEG. The study shows that new regimen could replace the standard intravenous treatment. A number of advantages with the new prophylaxis was a reason for us analysing the study as a non-inferiority study, i.e. if the new regimen was equally good as the existing one it would be preferable for other reasons. An oral solution of the antibiotic type Bactrim 20 ml directly injected into the stomach through the newly inserted PEG catheter could replace the previous standard prophylaxis with intravenously given Zinacef 1.5 g given 1 hour before the PEG was inserted. The results clearly show that the new regimen was at least as good as the standard regimen in the prevention of infectious complications. Advantages with the new regimen included it is cheaper price, easier to administer, fewer side effects, not given in vain whenever the PEG was not possible to insert (10% in the cases) and a better ecological pattern. We now want to assess whether this study had any clinical implications. Implementation studies are rare, but if research will actually lead to any changes in clinical practice, such studies should be conducted.

Aims

Assess that clinical implementation of the new antibiotic regimen based on the randomised clinical trial published in BMJ. Specifically this aim will be reached by:

- 1/ Clarifying to what extent the new antibiotic regimen that was recommended in BMJ study had any clinical influence in Sweden.
- 2/ Clarifying the potential patterns between the characteristics of the hospitals, i.e. comparing university hospitals with county hospitals and community hospitals, as well as a comparing hospital volumes of PEG's inserted per year and how that might have influenced the introduction of a new antibiotic regimen.

Methods

Data collection

- 1/ All hospitals which have inserted at least 5 PEGs per year during the years 2009-2011 will be identified in the Swedish Patient Registry (about 60 hospitals). PEG has the procedure code JBB10..
- 2/ The responsible physician for PEG insertions at each hospital will be identified.
- 3/ A structured telephone interview will be held with the responsible physician for PEG insertions according to a written form.

Questionnaire, see attachment

The structured interview will be tested by interviewing 3 clinically active physicians with knowledge in PEG.

Work plan

We will conduct telephone interviews in February 2013. Statistical analysis February-March 2013. Manuscript writing March 2013.

Collaborators

Jesper Lagergren, Fredrik Mattsson and Pernilla Lagergren and an the research nurse (interviewer) Isabella Linder-Rosén.

Reference

Blomberg J, Lagergren P, Martin L, Mattsson F, Lagergren J. Novel approach to antibiotic prophylaxis in percutaneous endoscopic gastrostomy (PEG): randomised controlled trial. *BMJ (Clinical research ed)* 2010;341:c3115.

Bilaga (Attachment)

Implementering av ny antibiotikaprofylax vid PEG i Sverige

Telefonintervju med PEG ansvarig

BASINFORMATION

Sjukhusets namn	
Klinik	
PEG-ansvariges namn	
PEG-ansvariges titel	
Kontaktuppgifter/noteringar	
Sjukhustyp	<input type="checkbox"/> Universitetssjukhus <input type="checkbox"/> Länsjukhus <input type="checkbox"/> Länsdelssjukhus <input type="checkbox"/> Annat:
Intervjun gjordes med	<input type="checkbox"/> PEG-ansvarig läkare (se ovan uppgifter) <input type="checkbox"/> Hänvisad till sekundärt ansvarig läkare: Namn: _____ Titel: _____ <input type="checkbox"/> Sjuksköterska vid endoskopienheten: Namn: _____ Titel: _____ <input type="checkbox"/> Annan: _____ Namn: _____ Titel: _____

Studieinformation till deltagare:

Vi genomför en studie för att undersöka hur regimen för antibiotikaprofylax ser ut i samband med PEG-läggning i Sverige. Jag undrar därför om det går bra att ställa några frågor till dig om hur det ser ut i din verksamhet.

Det är 8 frågor och intervjun tar ca X minuter.

INTERVJUFRÅGOR

Datum för intervju	
1. Ungefär hur många PEG lade ni in under förra året (år 2012)? Svar:	
2. Använder ni som rutin antibiotikaproylax vid PEG? <input type="checkbox"/> JA <input type="checkbox"/> NEJ (gå till fråga 5)	
3. Vilken antibiotikaproylax används för närvarande i 1:a hand? <input type="checkbox"/> Cefalosporin intravenöst (t.ex. Zinacef) <input type="checkbox"/> Bactrim mixtur i PEG <input type="checkbox"/> Annan Namn: _____ Administreringsväg: <input type="checkbox"/> intravenöst <input type="checkbox"/> peroralt <input type="checkbox"/> via PEG	
4. Om Bactrim används enligt ovan a) Vilket år införde ni denna profylax? År: _____ b) Varför införde ni denna profylax? Svar:	
5. Känner du till en svensk randomiserad klinisk prövning som publicerades i British Medical Journal (BMJ) som visade att Bactrim givet direkt i den nyinlagda PEGen kan ersätta intravenös antibiotikaproylax? <input type="checkbox"/> JA <input type="checkbox"/> NEJ	
6. Får jag skicka dig ett särtryck av studien? <input type="checkbox"/> JA <input type="checkbox"/> NEJ	
Vilken adress:	
Är det något övrigt du vill tillägga eller kommentera?	

Stort tack för att du tog dig tid att besvara frågorna!