

Rapport og sluttmelding Skjema for løpende rapport eller sluttmelding til de regionale komiteer for medisinsk og helsefaglig forskningsetikk (REK)

2011/2055-17

Dokument-id: 453665 Dokument mottatt 07.02.2014

Studie av livskvalitet ved användande av intermittent kateter (2011/2055)

1. Generelle opplysninger

a. Prosjekt

Studie av livskvalitet ved användande av intermittent kateter (2011/2055)

Prosjektmedarbeider

Ingen prosjektmedarbeidere

b. Prosjektleder:

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2. Rapport og etisk vurdering

Sluttmelding / publikasjon

The primary result of the study shows that SpeediCath Compact catheter use has a significant impact on the quality of life related to the use of intermittent catheter. An improvement of 17.0 points in the ISC-QoL score (0-100 points) was observed, which corresponds to 28 % increase compared to their usual coated intermittent catheter.

Sixty-three percent 63 of the subjects preferred the SpeediCath Compact catheter over their own catheter (p=0.007).

The general satisfaction with the catheter measured on a VAS scale was significantly increased with the SpeediCath Compact catheter compared to their usual coated catheter (p=0.037).

Patient compliance regarding the average frequency of catheterisations per day during the past 7 days was very high both at baseline and during the two test periods
The results revealed no safety concerns.

The study was conducted as described in the Clinical Investigation Plan with few deviations (please see attached Clinical Investigation Plan).

The primary result of the study confirms the hypothesis that the use of SpeediCath Compact coated catheter significantly improve the quality of life related to intermittent self catheterisation. An improvement of 17.0 points in the ISC-QoL score (scale from 0-100 points) was observed, which corresponds to a 28 % increase compared to their usual coated intermittent catheter.

3. Vedlegg

#	Type	Filnavn	Lagt inn dato
1.	Sluttmelding / publikasjon	Clinical Investigation Report -CP220.pdf	07.02.14