



Observational study comparing two different dilutions of “Braunol®” (active ingredient: povidone – iodine) regarding tolerability during preoperative ophthalmologic (“cataract”) surgery in adults

Waldemar Bauer, M.D., Augenklinik Starnberg, Germany

Background:

Braunol® „BSS“ 1,25 und 2,5% are povidone-iodine containing dilutions made from Braunol® (7,5 % povidone-iodine as active ingredient) in BSS (balanced saline solution)-buffer, and used to preoperatively disinfect the eye in ophthalmologic surgical interventions.

This application is principally described in the German Specialists Information Leaflet „Fachinformation“ for „Braunol®“.

The dilution is usually performed by a contract pharmacy on behalf of the “Augenklinik Starnberg”.

Methods:

This is an observational trial (“Anwendungsbeobachtung”) study, scheduled for 500 - 1.000 patients who undergo an elective ophthalmo-surgical intervention (e.g. cataract surgery) for which Braunol® in two different dilutions is applied.

Aim of the study is to evaluate the local tolerability of Braunol® in the said dilutions during introduction of anaesthesia upon assessment of patients’ reactions at topical application on the eye (i.e. reaction of conjunctivitis, of the periocular skin, pain assessment).

Status: 200 of 500 patients: data collected and interim statistical evaluation available.

Sponsor: B. Braun Medical AG, CH – 6204 Sempach