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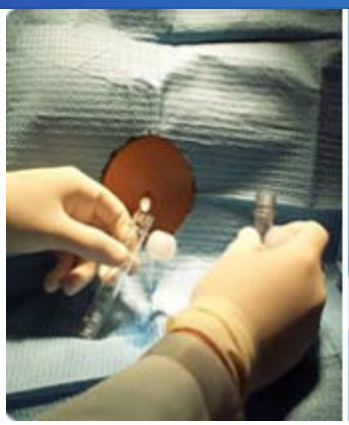
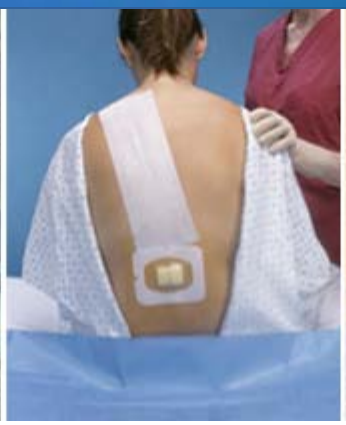
QPS Netherlands initiates Clinical Pharmacology Study with continuous CSF Sampling in Healthy Volunteers


QPS helps you navigate your way through CNS studies!

We would like to inform you that for the first time, QPS Netherlands will conduct a clinical pharmacology study that entails continuous CSF sampling from healthy volunteers. On September 14, 2011, the first healthy volunteer will undergo this invasive medical procedure as part of a clinical trial entitled: “A phase 0 validation study in healthy male volunteers assessing the safety and tolerability of serial CSF sampling and the evaluation of biomarkers related to Alzheimer’s disease in CSF and plasma”.

Timed interval CSF sampling from an indwelling catheter can be a valuable corroborative tool for PK assessment of drugs and the PD measurement of their effects. CSF sampling in studies of drug candidates for Alzheimer’s disease has been conducted to evaluate biomarkers such as acetylcholine, tau proteins, amyloid precursor protein (APP) and beta-amyloid fragments. The purpose of this study is to ascertain the feasibility and, in particular, the safety and burden for healthy volunteers of serial CSF sampling within the CRO environment, in order to establish a standardized research tool for future drug development studies.

QPS offers you 400 strategically located phase I beds in North America, Europe, and Asia. This is one of the world’s largest phase I site offerings of any CRO.

This study will be a validation study in healthy subjects. Eight healthy males aged between 55 and 75 years will be included. After having been determined eligible, subjects will enter the QPS CPU two days before starting the CSF sampling procedure. Hydration by drip infusion of 2L saline will be performed for 24 h before starting the CSF sampling procedure. For antithrombotic purposes, fraxiparine (nadroparine calcium) will be given 12 h and 36 h after intradural catheterization. CSF catheterization will be performed by a board certified anesthesiologist. Subjects will be required to remain horizontal during the sampling period and at least 24 hours after removal of the catheter. CSF and blood samples will be collected from the healthy volunteers by interval sampling over a 30 hour period.

Levels of biomarkers will be measured yielding valuable untreated baseline data of several analytes. Intermediate and exit interviews with the subjects will be performed by a pain expert and descriptively presented.

The diurnal pattern of the measured biomarkers will be investigated as well as the safety and tolerability of this invasive method in healthy volunteers in perspective of the necessity of developing research tools for the early clinical investigation of drugs for the treatment of neurodegenerative diseases.

Please do contact us to obtain more detailed information:

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