

BACKGROUND

Cerebrospinal fluid (CSF) collection is a valuable source of information for studying PK and PD of drugs targeting the CNS. QPS routinely applies this methodology and here we share our recent experience.

METHODS

- ▶ Identification of internal studies in which CSF was collected
- ▶ Per study, population, number of subjects, type of collection, purpose of collection and procedure related adverse events were recorded

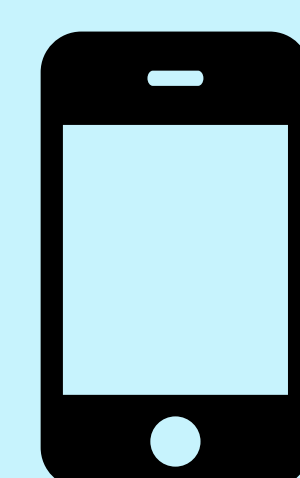
RESULTS

- ▶ 15 studies with CSF collection.
- ▶ 8 studies with 1-7 LPs per subject.
- ▶ 7 studies with serial sampling up to 36 hours
 - › 2 of these studies with twice serial sampling within the same subject
- ▶ 11 studies with in total 91 healthy volunteers
- ▶ 4 studies with in total 14 Alzheimer patients
- ▶ 5 studies for PK reasons only
- ▶ 10 studies for both PK and PD
- ▶ Post-dural puncture headaches were rare

CONCLUSION

- ▶ CSF sampling can be safely implemented in clinical pharmacology studies
- ▶ Serial CSF sampling can be done twice within the same subject

Cerebrospinal fluid collection in clinical pharmacology research: Invasive but **safe** and **invaluable** for biomarker and pharmacokinetic research



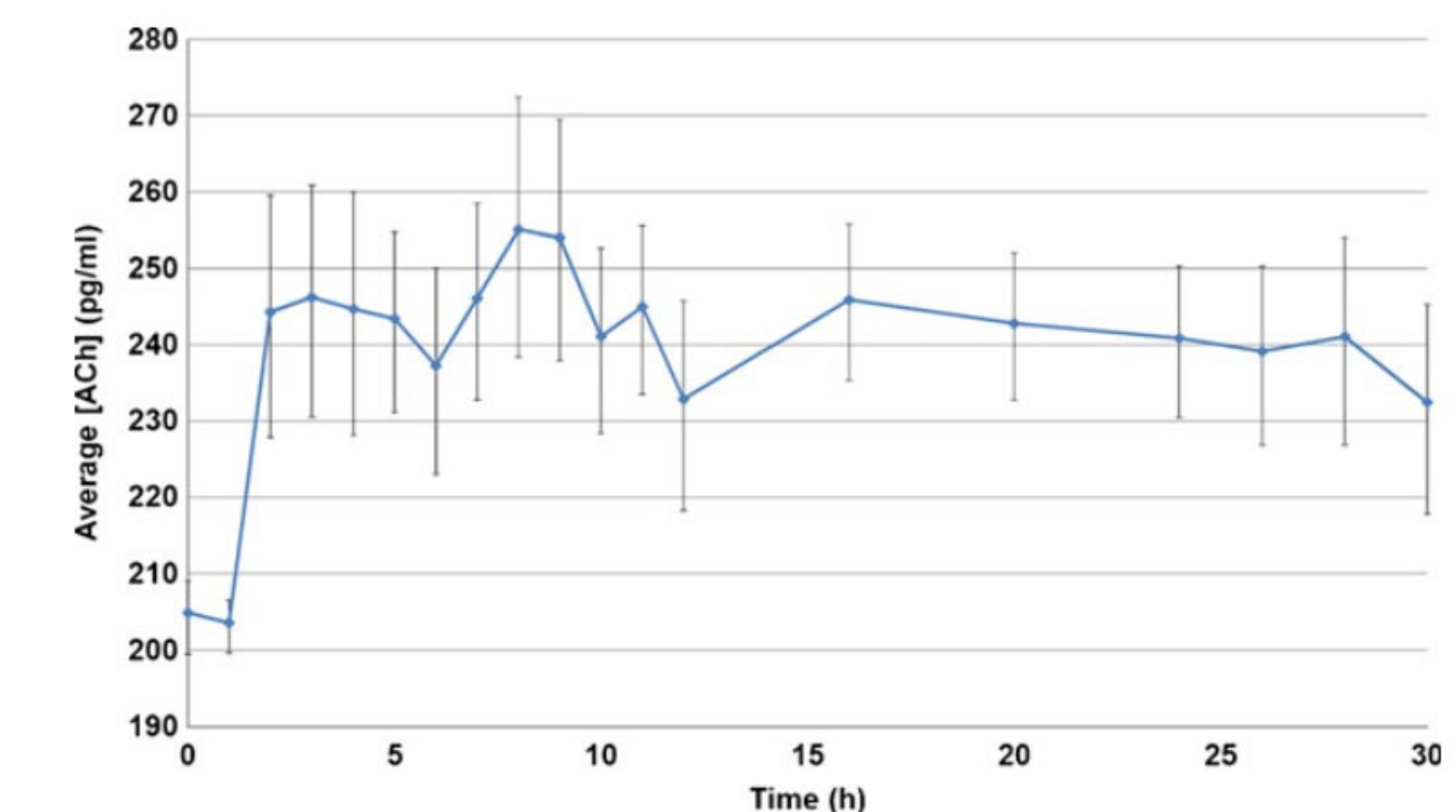
Take a picture to view the video



Insertion of canula, ready for sampling and actual sampling



Mean CSF Ach concentrations in n=7 healthy subjects



Example of twice plasma and CSF collection (on Day 1 and Day 25) within the same subjects

