

Summary attachment

Study: MORPHEUS

EudraCT no: 2020-002187-31

Status: preliminary termination due to recruiting difficulties

Sixteen healthy children completed the study; our goal was to include 36 patients. We knew the youngest age group would be difficult to recruit and all included patients were > 5 years of age. We tried different recruitment strategies (through public schools in the capital region) but many families found that 3 study days were too many.

Results:

16 patients were included, mean age 10.6 years old (SD \pm 3.14). Ten males (62.5%) and 6 females (37.5%). Mean weight of 40.4 kg (SD \pm 15.6) and mean height of 1.46 m (SD \pm 0.21).

All 16 completed 3 visits with 3 different dosages of melatonin i.e. 1,3 and 5 mg.

Salivary melatonin samples have been collected at three different dosage levels, and the dataset is complete for all included participants.

The acceptability of the medicine was measured with a modified Wong Baker scale (1 to 5). In addition, the SNPs *1C (-3860G>A) rs2069514 and *1F (-163C>A) rs762551 were analyzed for this CYP1A2 study.

Due to funding constraints, the saliva melatonin concentrations have not yet been analysed.

We plan to analyse the concentrations of melatonin and include the saliva concentrations and all covariates in a pharmacokinetic model.