Analysis highlights the importance of pharmacology measures in early clinical trials

October 4 2017

A new analysis published in the *British Journal of Clinical Pharmacology* indicates that 'first-in-man' clinical trial protocols in the Netherlands often lack a consistent consideration of pharmacokinetic and pharmacodynamic aspects in establishing drug doses.

These measures of pharmacology are important for determining a safe first dose to be administered to humans.

The analysis found that pharmacology endpoints were used more often in 2015 compared with 2007, but some trials still escalated until the maximum tolerated dose without a documented pharmacology assessment before moving to the next dose.

"Our study demonstrates that design choices in first-in-man trials are often not guided by pharmacology. This should be improved, as understanding the pharmacology of a new drug as soon as possible is essential, both for the safety of trial participants as for the further development of the drug," said Dr. Cornelis van den Bogert, lead author of the study.

More information: *British Journal of Clinical Pharmacology* (2017). DOI: 10.1111/bcp.13422