A new method to look for appropriate drug doses in early clinical trials

Date of summary: May 2019

The full title of this abstract is: Rethinking about the dose limiting toxicities (DLTs): They can be equivocal!

Researchers must look at the results of many types of studies to understand whether a drug should be prescribed to patients. This is because it is hard to prescribe to patients.

This summary reports the results of only one study. The results of this study might be different from the results of other studies that the researchers look at.

Researchers must look at the results of many types of studies to understand whether a study drug works, how it works, and whether it is safe to prescribe to patients.

More information can be found in the scientific abstract of this study, which you can access here: https://meetinglibrary.asco.org/record/175931/abstract

Who took part in this study?

More results from this study can be found here: https://meetinglibrary.asco.org/record/175931/abstract

In phase 1 studies, researchers look for the highest dose of the drug that people could take without having any unacceptable medical problems. This is known as the maximum tolerated dose (MTD for short).

Early studies of the effects of drugs on people are called phase 1 studies. At the right dose range, drugs can be both safe and effective, but if the dose is too high, drugs can become toxic. It is important for researchers to find this “safety window”.

Researchers can have difficulties defining DLTs. For example, a person could have a medical problem that researchers define as a DLT, when it was actually caused by another health condition.

Phase 1 studies only include a small number of people so, if DLTs are not defined correctly, this could lead to errors in the study results.

In this study, the researchers created a new method to help determine what DLTs should be recorded to the practical experience of the doctors involved in the study. This method included a computer program for finding toxicities on the maximum tolerated dose in different ways to find the maximum tolerated dose.

This summary describes how this method worked in a computer model.

In this study, the researchers created a new method to avoid these potential issues.

• They looked at information about DLTs based on the practical experience of the doctors involved in the study.

• They also looked at some specific medical problems in the statistical model in different ways to find the maximum tolerated dose.

Researchers find the maximum tolerated dose by looking for medical problems that are serious enough to prevent an increase in dose. These effects are called dose-limiting toxicities (DLTs for short).

What were the results of the study?

The researchers used a computer model to test their theory. The method hasn’t been tested in real life yet and the study did not include real people.

The model showed that the new method could improve the chance of finding the correct maximum tolerated dose.

Please note that this summary only contains information from the full scientific abstract:
https://meetinglibrary.asco.org/record/175931/abstract

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What did this study look at?

What was the main conclusion reported by the researchers?

This technique could help researchers to find the maximum tolerated dose more accurately in phase 1 clinical trials.

Who sponsored this study?

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Further information

For more information on this study, please visit:
https://meetinglibrary.asco.org/record/175931/abstract

For more information on clinical studies in general, please visit:
https://www.clinicaltrials.gov/ct2/about-studies/learn
http://www.cancerresearchuk.org/about-cancer/what-clinical-trials-are

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