



Learning Early About Peanut Allergy (LEAP)

Selected as the 2015 David Sackett Trial of the Year

Wendy Parulekar and Scott Evans

Learning Early About Peanut Allergy Trial (LEAP), a randomized controlled trial, is the awardee of the prestigious 2015 David Sackett Trial of the Year Award, presented annually by the Society for Clinical Trials. Gideon Lack, Senior Investigator on the LEAP Trial accepted the award on behalf of the LEAP Trial team. Gideon Lack, a Professor of Paediatric Allergy, King's College London, Head of the Clinical Academic Paediatric Allergy Service, Guy's & St Thomas' NHS Foundation Trust, presented the LEAP trial on May 17th, 2016 at the Society's 37th Annual Meeting in Montreal, Canada.

Peanut allergy is a major health issue. The prevalence of peanut allergy among children in Western countries has doubled in the past 10 years, and is rising in Africa and Asia. The LEAP Trial was conducted in the UK and enrolled 640 children aged 4-11 months who were considered at high risk of developing peanut allergy due to pre-existing severe eczema and/or egg allergy. To determine whether peanut consumption or avoidance is the most effective strategy to prevent peanut allergy, half of the children were asked to eat peanut-containing foods three or more times each week, and the other half to avoid eating peanut until 5 years of age. Participants were monitored throughout this period during recurring visits with healthcare professionals. Adherence to consumption or avoidance advice was assessed using a telephone food frequency questionnaire at regular intervals and by measuring peanut levels in the child's home environment.

The researchers assessed peanut allergy at 5 years of age with a supervised, oral food challenge with peanut. They found that the overall prevalence of allergy in all children asked to consume peanut was 3.2% versus 17.2% in the avoidance group. This represents an overall 81 percent reduction of peanut allergy in children who began early, continuous consumption of peanut compared to those who avoided peanut. The LEAP Trial showed that early introduction of peanut significantly decreased the frequency of the development of peanut allergy among children at high risk for this allergy, thus identifying an effective approach to managing a serious public health problem. LEAP served as the basis for new guidelines from the American Academy of Pediatrics recommending early peanut introduction in high- risk children.

Each year since 2008, the SCT has been awarded to a randomized, controlled trial published (either electronically or in print) in the previous calendar year that best fulfills the following standards:

- It improves the lot of humankind.
- It provides the basis for a substantial, beneficial change in health care.
- It reflects expertise in subject matter, excellence in methodology, and concern for study participants.
- It overcomes obstacles in implementation.
- The presentation of its design, execution, and results is a model of clarity and intellectual soundness.

Nominations came from Society members, investigators, and interested scholars from around the world.

The 2015 David Sackett Trial of the Year selection committee included Kay Dickersin (Chair), Marion Campbell, Christopher Coffey, Scott Evans, Tianjing Li, Wendy Parulekar, Paula Williamson, and Janet Wittes.

The 2016 Trial of the Year Selection Committee will issue a call for nominations in fall, 2016. Visit www.sctweb.org for updates.

About the Society for Clinical Trials: The Society for Clinical Trials, created in 1978, is an international professional organization dedicated to the development and dissemination of knowledge about the design, conduct, analyses, and reporting of government and industry-sponsored clinical trials and related health care research methodologies. Visit www.sctweb.org.

About the David Sackett Trial of the Year: Find a list of past Trials of the Year on www.sctweb.org.