babyTAPE

WHY WAS THIS STUDY NEEDED?

Weight is the primary indicator of health outcomes in preterm and full-term infants. However, in many areas, community health workers and health care providers do not have access to calibrated scales to take measurements of infant's weight in the case of an emergent need. It can also be difficult or impossible to account for or remove life-saving medical equipment from infants in intensive care units to take their weight on a scale. There are several existing weight estimation formulas for children, but most are for older children and cannot be applied to infants 0-90 days old. The babyTAPE studies developed a formula and device to fill this gap and accurately estimate the weight of infants.

WHAT HAPPENED DURING THE STUDY?

To identify the babyTAPE formula, researchers used measurement data from over 2,000 infants collected from several hospitals in 2015-2016. They found that head circumference and chest circumference (in millimeters) showed the best correlation to actual weight. A simple formula using these two measurements was created. Accuracy of the formula was evaluated using the percentage of infants whose estimated weight fell within 10% and 15% of their actual weight.

With the measurements identified and formula created, researchers developed the babyTAPE device. The device is a flexible, paper-based measuring tape printed on both sides. One side is designated for head circumference measurement and the other for chest circumference measurement. The babyTAPE device was tested on 486 infants by 15 raters at three U.S. hospitals. The device was validated using the percentage of infants whose estimated weight was within 10% and 15% of their actual weight. Any challenges that raters had with the device were also noted.

WHAT HAPPENED NEXT?

The results of this study were sent to the U.S. Food and Drug Administration (FDA), a government agency that approves drugs and devices used to treat patients. The findings were used to make decisions on approval of the device. This new device gives doctors the information they need to help them give the safest, most effective treatment to children.

WHERE CAN I LEARN MORE ABOUT THIS CLINICAL TRIAL?

A summary of the results for this trial can be found at pediatrictrials.org. If you have additional questions, please speak with the doctor or staff at your study site.

** This summary was completed in [September 2022]. Newer information since this summary was written may now exist. This summary includes results from two studies. Other studies may find different results.*

WHAT KIND OF STUDY WAS THIS?

The babyTAPE studies were multi-site studies that took place in eight hospitals across the United States. The first study tested the accuracy of the weight estimation formula on 2,097 infants 0-90 days old. The second study tested the babyTAPE device for accuracy and ease of use. The device was tested on 486 infants 0-90 days old.

WHAT SIDE EFFECTS DID INFANTS HAVE?

There were no side effects associated with this study.

WHAT WERE THE STUDY RESULTS?

The head circumference and chest circumference measurements taken without the babyTAPE device predicted within 10% of actual weight 84% of the time and within 15% of actual weight 94% of the time. Measurements taken with the babyTAPE device predicted within 10% of actual weight 86% of the time and within 15% of actual weight 99% of the time. All health care workers who tested the device were confident or very confident with their estimates and found it easy to use. To researchers' knowledge, babyTAPE is the first device that has been successfully validated for weight estimation of preterm and full-term infants.

WHO CONDUCTED THE STUDY?

The study was conducted by the Pediatric Trials Network (PTN), a group of more than 100 research sites around the world that are working to find the safest and most effective doses of commonly used medicines for infants and children. Children aren't just little adults. Their bodies are growing and changing, meaning that they process medicines differently than adults do. The PTN works to make sure doctors and families have the information they need to give children the right dose: one that will get them well and keep them safe.

The study was made possible with support from the Eunice Kennedy Shriver National Institute of Child Health and Human Development.

PEDIATRIC TRIALS NETWORK

Making drugs safer & more effective for use in the youngest patients