

Effective GH Replacement with Somapacitan in Children with GHD: REAL4 2-year Results and after Switch from Daily GH

Plain language summary

To help children grow, the body naturally makes a chemical called “growth hormone”. Not all children are able to make enough growth hormone in their bodies; this is a condition called “growth hormone deficiency”. Because of this condition, these children grow a lot slower compared to other children their age and, as a result, do not reach the same height as adults.

To help children living with growth hormone deficiency, doctors prescribe a medicine that contains growth hormone. This medicine has been safely used in children for 40 years but the children need injections under the skin every day for the medicine to work. Daily injections of growth hormone medicine have been shown to be a burden for both the children living with growth hormone deficiency and their families. REAL4 is a study where doctors looking at a new growth hormone medicine, called “somapacitan”, that only needs to be injected once a week.

Results from children living with growth hormone deficiency taking this new medicine for one year in the REAL4 study showed that it is as well-tolerated and works as well as taking daily injections of growth hormone medicine. This publication looks at results for the children in the REAL4 study after 2 years of taking somapacitan. It also looks at children who were taking daily injections of growth hormone medicine for the first year and then switched to taking somapacitan for the second year.

In total, 127 children continued to take somapacitan in the second year. There were 67 children who took daily injections of growth hormone medicine in the first year and then switched to taking somapacitan in the second year. The children participating in the REAL 4 study were living across the world in 20 different countries in either Europe, Asia or the Americas.

After this second year of treatment, the doctors found that the children in both groups grew to a similar extent. They also found that the children in both groups did not have many side effects because of the treatment. Any side effects that they did have were mild and similar to side effects seen in other studies looking into growth hormone medicines in children with growth hormone deficiency.

Questionnaires were given to the parents of children who switched from taking daily growth hormone to somapacitan in the second year. The questionnaire asked which treatment they preferred; daily growth hormone or once-weekly somapacitan. Almost all (45 out of 50) who responded preferred somapacitan and no-one preferred daily growth hormone treatment. Some of the reasons for this mentioned by the parents included the fewer number of times needing to give injections when taking somapacitan and being less worried about remembering to give injections. Most parents (35 out of 45) who preferred somapacitan treatment also thought they would be better at remembering to give the once-weekly injections instead of the daily injections.

In conclusion, this REAL4 study shows that somapacitan is effective and well-tolerated into the second year of use. It also shows that most parents whose children have switched from daily injections of growth hormone prefer once-weekly somapacitan. These results help to show that somapacitan could be a good alternative treatment to the current daily injections for children living with growth hormone deficiency.