

Children taking unapproved sleep meds for several years

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More children are being prescribed melatonin as a sleep medication, although it is not approved for this use and little research exists on its long-term side effects.

Our bodies produce the hormone melatonin, which contributes to our ability to fall asleep. Melatonin production increases at the onset of dusk and tells our bodies it is time to get ready for bed. The level decreases as morning approaches, and ideally we awaken refreshed and ready for a new day.

Melatonin pills increase the hormone concentration in the blood, and they are used to help people with sleep difficulties fall asleep more easily. In the EU, this medication is only approved for individuals over 55 years old for up to 13 weeks.

However, a recent survey to measure the prevalence of melatonin use among Norwegian children between 4 and 17 years old is now available. It shows that melatonin use has increased annually between 2004 and 2012, with some children as young as four years old taking this medication for several years.

Other possible effects

Several studies have shown that melatonin affects more than sleep, including sexual development and reproduction. The hormone led to a delayed onset of puberty in several rodent and primate experiments. Melatonin administered to sheep caused an increased ovulation rate, according to a research article in the February 2015 issue of the *Journal of Paediatrics and Child Health*.

“The question is whether melatonin may affect puberty and reproduction in humans. This is especially important for children treated with the hormone over extended periods,” said Ingeborg Hartz. She is a researcher at Hedmark University College and the Norwegian Institute of Public Health (FHI). Her study is part of a Department of Pharmacoepidemiology project at FHI.

To date, no clear effects on human puberty through melatonin use have been found. Jan Egil Wold supervises the child and adolescent psychiatry department at Hospital Levanger. He says that he never prescribes this medication for long-term use. “Even though no one has proven harmful effects on children, I find that the documentation is inadequate. I still haven’t read any good studies on the subject,” he says.

A Dutch study followed almost 70 children who had been on melatonin for just over 3 years and did not find that long-term treatment caused any disturbances in the onset of puberty. Hartz says that this is the only study she knows of that has examined the effects of long-term melatonin use on pubertal development in children and adolescents.

Australian researcher David Kennaway has criticized the study for being too small and ending when only a third of the children had turned 13 years old, and many who had not reached puberty yet. Hartz agrees with

his criticisms and says, “The onset of puberty varies widely from person to person, so you need a lot of participants in a study to determine effects.”

More melatonin prescriptions for children

Hartz has led the efforts to map the prescription rate of melatonin medications among children and adolescents in Norway from 2004 until now. She also linked the use of the melatonin with the children’s diagnoses, to see why they were taking these medications.

The survey showed that 8000 prescriptions were dispensed to children ages 4-17 in 2012. This reflects an increase in use from 3 per 1000 boys in 2004 to 11 per thousand in 2012. The increase for girls went from 1.5 to almost 8 per 1000 during the same time period.

“The youngest children were between 4 and 8 years old when they began using melatonin. This age group included the most long-term users, with around half of them on the medication for over three years. It seems that use is widespread among children who are about to enter puberty,” says Hartz.

ADHD diagnoses most prevalent

Nine of ten long-term users from the study also had a psychiatric or neurological diagnosis, with the majority being ADHD diagnoses. Hartz says that melatonin use must be viewed in light of these diagnoses.

“If the pills help children sleep, some people may feel that it’s fine to use them even though we don’t know enough about the long-term effects. But prescribing melatonin for children comes with a clear responsibility,” she says.

Steinar Madsen is the Medical Director at The Norwegian Medicines Agency (NOMA). He says NOMA is very interested in how melatonin treatment correlates with ADHD medications.

Melatonin pills are non-addictive, which Madsen believes makes it a better alternative to many other sleep medications, despite not being approved for use by children and adolescents.

“Sleep difficulties can be a side-effect of ADHD medication. For short periods, using these medicines shouldn’t pose a problem,” he says, “but we would like to see more follow-up studies of children who are on them for several years.”

Debate encouraged

“Sleep problems in children should not be viewed as an isolated issue — we have to look at the whole picture. There are complex reasons why children have difficulty sleeping,” says Anne Kristine Bergem, a psychiatrist and the President of the Norwegian Psychiatric Association.

She finds it a disturbing trend that so many children and adolescents are on sleep medication for long periods and thinks that they could benefit from thorough psychological examinations, instead of immediately being put on medication.

“One should never start taking a medication without knowing the duration, whether as a child or an adult,” Bergem says. She urges the Norwegian Association of General Practitioners and the Specialist Health Services to take up the issue of melatonin treatment in their discussions.

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 [About 8000 prescriptions for melatonin were written for children in 2012. \(Illustration photo: Colourbox\)](#) [8]

 [Ingeborg Hartz is a researcher at Hedmark University College. \(Photo: Private\)](#) [9]

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