
Press release

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Cost effectiveness and efficacy of the Hemics HandScan will be studied in multi-center tight control treatment of Rheumatoid Arthritis.

Eindhoven, the Netherlands, March 31, 2014 – Hemics BV announces today a multi-center clinical study to evaluate the cost effectiveness and efficacy of its HandScan in tight control treatment of Rheumatoid Arthritis (RA). The study will be performed at the University Medical Center (UMC) Utrecht and four general hospitals in the same region, partners of the SRU (Stichting Reumaonderzoek Utrecht), in collaboration with the Dutch Arthritis Foundation and Hemics. In an earlier study in UMC Utrecht using Ultrasound (US) measurements as gold standard, a prototype of the HandScan showed superior performance in detecting joint inflammation when compared to clinical examination, suggesting that HandScan is a better tool for monitoring rheumatoid arthritis [1]. The present study will determine whether this is indeed the case.

Tight control (frequent monitoring and adapting the medication when necessary) of RA in the first period of the disease strongly reduces the progression of irreversible tissue damage later in the disease [2,3,4]. Implementing tight control in clinical practice is a challenge, as frequent monitoring generally burdens the rheumatologist due to the extra consultations. Furthermore, existing monitoring methods are expensive, labour intensive or operator dependent. The HandScan is objective and fast (under two minutes), allowing for implementation of effective tight control. More than one hundred patients with recently diagnosed RA will be included in the study. Disease activity monitoring will be monthly over a period of two years, and treatment decisions will be based on either the generally used DAS28 score, or (quicker and expectedly more sensitive) HandScan measurement. The study is supported by the Dutch Arthritis Foundation and the Dutch government through an LSH Impulse subsidy [5]. Five HandScans will be placed at UMC Utrecht and 4 regional general hospitals within the collaboration of the SRU.

Hemics is the first company in the world to bring to market a non-invasive optical imaging method that supports the rheumatologist in objective assessment of inflammatory status in RA. The HandScan works by measuring the blood flow in 22 joints of the hands and wrists using diffuse optical transmission in combination with a patented blood flow modulation method. Based on optical technology the device poses no risk for the patient. Market introduction is expected mid 2014 (pending CE mark).

Prof. Dr. Jaap van Laar, Head of the Department Rheumatology and Clinical Immunology at UMC Utrecht and principal investigator: "We look forward to evaluate Hemics' novel technology in a tight control setting. Frequent monitoring and fine-tuning the medication as is done in tight control reduces the impact of RA on patient's

functional ability and quality of life in the long run. The HandScan has the potential to enable widespread implementation of tight control, also in busy practices. "

Dr. Ingrid Lether, Manager Research and Innovation at the Dutch Arthritis Foundation comments: "The world's first evaluation of this new Dutch technology in a tight control setting will take place here in the Netherlands in this study. We are excited to help make that happen, as it has the potential to positively impact lives of RA patients everywhere."

Dr. Wouter Rensen, Hemics' VP Clinical Application, comments on the study: "UMC Utrecht has helped to evaluate our technology early on and we are very excited to continue to work with such an outstanding center, this time to establish evidence of the HandScan's usefulness in implementation of tight control in clinical practice. The involvement of four non-academic collaborating hospitals will furthermore enable us to show the usefulness not only in an academic center but also in day-to-day practice in general hospitals. We are very happy with the involvement and support of the Dutch Arthritis Foundation which represents the interests of arthritis patients. It strengthens our belief that our technology can make a difference in the lives of many RA patients."

About Rheumatoid Arthritis (RA) - RA is a chronic inflammatory disease, affecting between 0.5% and 1% of the population worldwide. RA is a progressive disease with currently no cure, making the disease a chronic condition. RA is associated with regular flare ups and if left untreated these will cause irreversible joint damage and ultimately severe joint deformation and loss of function. The treatment of RA is staged. Initially the patient receives classical disease modifying anti-inflammatory drugs. If this treatment becomes ineffective, different and more advanced drugs (e.g. biologics, such as anti-TNF antibodies) are employed. Treatment is guided by monitoring of disease activity, and if done adequately, irreversible joint damage can be prevented and discomfort due to the disease and drug side effects can be limited. As such monitoring of disease activity helps to reduce the overall treatment costs which is important given the chronic nature of RA.

About Hemics - Hemics B.V. is a medical device company active in the field of Rheumatoid Arthritis (RA). Hemics' ambition is to improve the quality of life of patients with RA by creating imaging devices that support the rheumatologist in monitoring and treatment of this disease. Hemics' systems are based on patented optical inflammation detection technology, a non-invasive, fast and operator independent method that supports rheumatologists in objective assessment of inflammatory status, a key parameter in the treatment of patients with RA. Hemics is a Dutch company that was founded as a spin-off of Royal Philips where the inflammation detection technology was invented. For more information, please visit www.hemics.com.

About Dutch Arthritis Foundation - The Dutch Arthritis Foundation is the largest independent financer of arthritis research in the Netherlands and funds around 60% of independent arthritis research. Dutch Arthritis Foundation supports research in a broad spectrum of rheumatic diseases, with a focus on rheumatoid arthritis, osteoarthritis, spondylarthropathies, Sjögren's disease and juvenile arthritis. The whole spectrum of research is covered, from fundamental to clinical with a strong emphasis on translational research.

References:

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- [4] V. Rantalaiho, et al. (2009). Arthr Rheum, vol. 60, no 5, pp. 1222-1231.
- [5] <http://www.lifescienceshealth.com/news/details/item/10-lsh-impuls-aanvragen-geselecteerd-voor-honorering.html>

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