



Breakthrough for Antisecretory Factor at the world congress for Ménière's disease.

A total of 550 ENT specialists from 52 countries had gathered in Rome the 17th-20th of October to participate in 7th International Symposium on Ménière's Disease and Inner Ear Disorders.

The clinical efficacy of Antisecretory Factor (AF) in Ménière's disease was presented. This took place at the minisymposium: Antisecretory Factor: A clinical innovation in Ménière's Disease?

The clinical studies, which were presented, answered with a resounding Yes!

AF is available as SPC Flakes and Salovum

SPC can be said to be a kind of vaccination, as it activates and stimulates the production of AF in the body. SPC Flakes are manufactured by a patented method, a hydrothermic process.

Salovum is an external supply of AF. A special breed of hen is given AF-activating feed. This means that the hens achieve a high level of AF, which they pass on to their chicks through the egg yolk which is harvested and spray dried.



SATURDAY OCTOBER 17th, 2015

AUDITORIUM

MiniSymposium: 14.30 - 15.00

Antisecretory Factor - a clinical innovation in Ménière's disease?

(with the unconditional contribution from POA Pharmaceuticals, Sweden)

14.30-15.00

Moderator: J.G. Bruhn (Tomelilla, Sweden)

14.30-14.35 Antisecretory factor and medical foods - novel therapy concepts

J.G. Bruhn (Tomelilla, Sweden)

14.35-14.45 Antisecretory factor-inducing therapy improves patient-reported functional levels in Ménière's Disease

S.C. Leong, T.H. Lesser (Liverpool, UK)

14.45-14.55 SPC Flakes in prophylaxis of Ménière's disease

R. Teggi, V. Marcelli (Milano, Italy)

The Ménière-symposium on AF in numbers

Gothenburg pilot study

Number of patients 24, whereof 12 had improved

Hanner P, Rask-Andersen H, Lange S, Jennische E

Number of patients 27, whereof 14 had improved

Lesser T, Leong S, Narayan S

Number of patients 39, whereof 23 had improved

Teggi R, Marcelli V

Number of patients 25, whereof 16 had improved (study is on-going, not published)

Sweden

Jan G Bruhn, farm. dr and adjunct professor at the Linné University in Kalmar, introduced his lecture with a brief look



at past events and a definition of AF.

Antisecretory factory (AF) is a protein that is excreted in plasma and other tissue fluids in mammals.

More than 20 years of Swedish basic research (Lange and Lönnroth) is behind the discovery of this protein (41-kDa), which has an important role for different secretory and inflammatory conditions.

Protein AF has a powerful ability to counteract different types of secretion. The clinical importance has been studied in different diseases where a disturbed fluid homeostasis is of vital importance, e.g. different bowel diseases, diarrhoea and Mb Ménière.

Protein AF also has anti-inflammatory properties, which has been shown in studies on inflammatory bowel disease (IBD), rheumatic diseases and mastitis (inflammation of mammary glands).

Newly published American studies demonstrate the likely involvement of protein AF in regulating our immune system.

The research has led to medical foods of clinical value. One of these products is SPC-Flakes, Specially Processed Cereals.

Jan Bruhn then outlined the first Swedish studies. After an introductory pilot study (1) the first controlled clinical Ménière study was started by Hanner P, Rask-Andersen H, Lange S, Jennische E Hanner P, Rask-Andersen H, Lange S, Jennische E. (2).

The result meant that AF started to be used by patients and led to more clinical trials with the disease.

Hanner, Rask-Andersen, Lange and Jennische undertook a randomized, double blind, placebo-controlled study on 51 adult patients, 27 patients on AF (SPC Flakes) and 24 on placebo diet.

The severity of disease was classified according to the American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS) classification system.

14 of the 27 patients in the SPC Flakes group testified to reduction of vertigo compared to 2 patients in the control group ($p < 0,001$). No side effects were reported.

Great Britain

Tristram Lesser consultant at the Department of Otorhinolaryngology, Head and Neck and Skull Base Surgery, University Hospital Aintree, Liverpool presented the study conducted by him and co-workers. (3)



– Our study (3) includes 39 patients (22-80 years) with the diagnosis Ménière's disease in a randomized, double blind, placebo controlled crossover study. The result was measured with the Functional Level Scale, an evaluation tool that has been used and accepted internationally for more than 20 years for Ménière's disease (see below).

– The study was done in such a way that the patients were given 3 months supply of SPC or placebo oats in a similar looking preparation. Neither the doctors nor the patients knew what the packages contained. After a short "wash-out period" of two weeks the patients were given the other of the two alternatives for an additional three months of use.

Anti sekretorisk Faktor

AF regulates the fluid and ion transport over cell membranes in different organs of the body, probably by regulating the permeability in the channels responsible for water and ion transport.

Thus, AF has a fundamental influence over diseases where secretion is of importance

The presence of AF protein in the inner eye indicates that AF regulates the fluid pressure of endolymph and thereby reduce the symptoms of Meniere's disease



Impressive improvement from 5 to 2

The result is positive. A shift on the Functional Level Scale from 5 to 2 is a very impressive improvement especially since the patients who took part in the study had tried other treatments but had failed, before the SPC treatment.

Ménière patients in the study are selected from the minority of cases that are remitted to specialist clinics. The majority of patients with milder symptoms are handled by the primary care.

– The patients showed significant improvement with SPC Flakes. Several patients reported that they could feel their condition deteriorate when they switched from (as they believed) active SPC to placebo.

AAO-HNS Ménière's Disease Functional Level Scale

1. My dizziness has no effects on my activities at all.
2. When I am dizzy, I have to stop what I am doing for a while, but it soon passes and I can resume activities. I continue to work, drive, and engage in any activity I choose without restriction. I have not changed any plans or activities to accommodate my dizziness.
3. When I am dizzy, I have to stop what I am doing for a while, but it does pass and I can resume activities. I continue to work, drive, and engage in most activities I choose, but I have had to change some plans and make some allowance for my dizziness.
4. I am able to work, drive, travel, take care of a family, or engage in most essential activities, but I must exert a great deal of effort to do so. I must constantly make adjustments in my activities and budget my energies. I am barely making it.
5. I am unable to work, drive or take care of my family. I am unable to do most of the active things that I used to do. Even essential activities must be limited. I am disabled.
6. I have been disabled for one year or longer and/or I receive compensation (money) because of my dizziness or balance problem.

Italy

Professor Roberto Teggi, ENT department, San Raffaele Scientific Institute, Milan explained the work he and his colleague, V. Marcelli at Centro Ospedaliero "San Giovanni Bosco" had conducted with AF.

25 patients with Ménière's disease take part in their study that were selected from two university centres from the



group of patients who had responded poorly to betahistine 48 mg/day during the last three months.

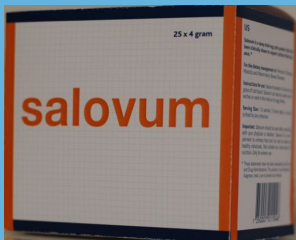
During the following three months the patients

received a combination treatment with betahistine and AF in the form of SPC Flakes (1 g/kg/day).

Results in brief

Vertigo attacks reduced from 1.8 ± 0.7 to 0.6 ± 0.3 per month ($p \leq 0.001$). In particular, 8 cases showed an Efficacy Index lower than 25 per cent (32 per cent), 8 cases in the interval between 25 and 50 per cent, 5 cases (20 per cent) in the interval 50 and 75 per cent and 4 cases (16 per cent) higher than 75 per cent. In addition 4 patients (16 per cent) reported a reduction in the duration of vertigo attacks.

"Our data confirms the studies that have been previously published; a significant reduction of vertigo attacks during treatment. 16 of our 25 patients had a significant response to treatment with SPC Flakes."



Salovum®, 25x4 g

Salovum® is a spray dried egg yolk powder with a high concentration of the protein Antisecretory Factor (AF).

AF is primarily used for acute treatment or in the initial treatment of patients with suspected low levels of AF

Instruction for use

Salovum powder is stirred into a glass of cold liquid. The best result is obtained with fruit juice preferably with pulp. Salovum can also be used in sandwiches or used in the mixture for egg dishes.

SPC-Flakes®, 450 g

SPC Flakes is produced through a patented process involving hydrothermal treatment. No additives are needed in the process. These enzymatically activated specially processed cereals (SPC) stimulates the endogenous production of the AF protein in the body and protects against secretion and inflammation.

Instruction for use:

SPC-Flakes can be eaten with dairy products such as yoghurt or milk. SPC-Flakes can also be cooked as porridge either alone or with other grain products. SPC-Flakes can be mixed with flour and used for the baking of cakes and bread.

Dosage:

1 g per kg of bodyweight daily or as prescribed by the doctor. The dosage should be divided into 2-3



The moderator's summary

Jan G Bruhn expressed his satisfaction with the minisymposium.

– Our minisymposium was appreciated and well attended. 250 specialists from the whole world listened and saw the research results from three mutually independent centres in three different countries, results which all pointed in the same direction.

– I was especially pleased with Professor Tristram Lesser from Liverpool, who with complete honesty introduced his lecture by stating the original purpose of his clinical trial; to prove that AF doesn't work. Very soon he had to take another position, he admitted.

– Very delightful was also Professor Roberto Teggi from Milan who not only could show convincing research results but also is ready to continue further research. He will go on to examine non-responders.

– A lesson to draw from the minisymposium is that our foods not only work as nutrition. They can often have a healing effect.

References

1. Antisecretory Factor: A Clinical Innovation in Meniere's Disease?

Per Hanner, Eva Jennische and Stefan Lange.
Taylor & Francis healthsciences

2. Antisecretory factor-inducing therapy improves the clinical outcome in patients with Ménière's disease.

Hanner P, Rask-Andersen H, Lange S, Jennische E.
Acta Otolaryngol 130(2): 223-227, 2010.

3. Antisecretory Factor-Inducing Therapy Improves Patient-Reported Functional Levels in Meniere's Disease
Samuel C. Leong, MPhil, FRCS(ORL-HNS); Surya Narayan, MS, DLO, FRCS(ORL-HNS); Tristram H. J. Lesser, MS, FRCS

Annals of Otology, Rhinology & Laryngology 2013; 122:

A satisfied congress president

Professor Maurizio Barbara, MD, PhD from Sapienza University in Rome was the president of the symposium.

He expressed his great satisfaction when talking the reporter from POA

Pharma:

– After 22 years the world congress on Ménière's disease is back in Rome. I take it as a sign the research at Sapienza University is appreciated.

– The medical advancements for the treatment of Ménière's disease has in time led to less need for surgery.

– Another area under rapid development is diagnostic methods such as MRA in case of endolymphatic hydrops in the inner ear.

– I am also happy to see AMMI-onlus the national patient organization for Ménière among the exhibitors.



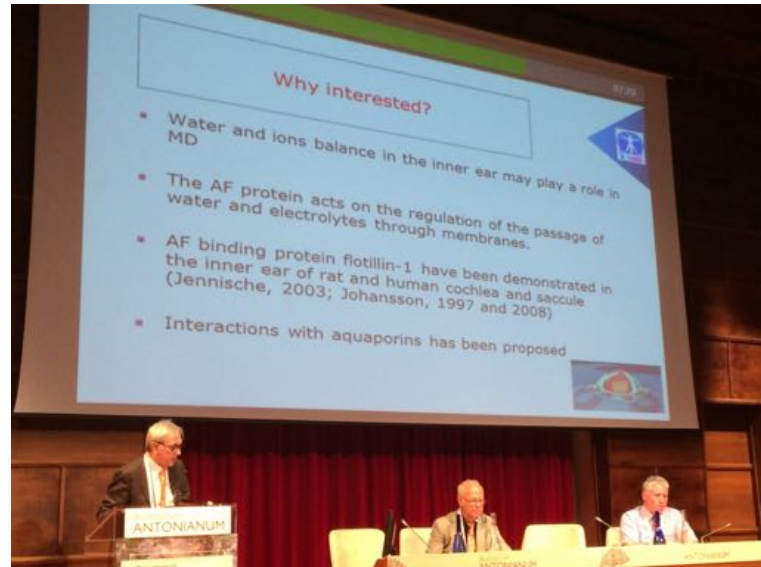
In conclusion professor Barbara told about spending three years at the Karolinska Institute from 1988. "I had a PhD in Inner Ear Function".

La Sapienza ("Wisdom") in Rome is the largest university in Europe and one of the largest in the world in terms of number of students.

The University was founded in the year 1303 by the pope Bonifatius VIII.

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La Sapienza ("Visheten") i Rom är Europas största universitet och ett av de större i världen i antal



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Order the symposium as an audio presentation. can be sent via email to be downloaded.

Order a visit from a POA specialist for a seminar around AF.

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