Summary

Following careful study of the literature and other available information, the Swiss Study Group for Complementary and Alternative Methods in Cancer (SKAK) and the Swiss Cancer League (SCL) have no proof that the cancer immunotherapy Galavit can cure carcinogenic diseases. We must therefore advise cancer patients against relying on the curative effect of this method and highlight possible dangers which this therapy may pose.

Claims of the suppliers

According to information contained on a website in February 2001, Galavit has prolonged the survival time of patients suffering from cancer and markedly improved their quality of life. In many cases, the suppliers say, the primary tumour has ceased growing and the growth of metastases was able to be prevented. Shortly after starting the therapy, more than 80% of patients had put on an average of 1.5 to 2kg in weight as is stated.

It has supposedly been proven that Galavit
- reduces the side-effects of radio- and chemotherapy,
- stimulates macrophages, which results in increased interleukin production
- modulates the basement membrane, thereby inducting a cellular immune reaction
- modulates the cytotoxicity index of NK cells: high values were decreased and low values were increased.

According to the information on the Russian package circular Galavit inhibits the hyperactivity of macrophages, yet information from the Institut Harz states that Galavit activates the macrophages (quote according to 14).

Discovery

The medicine is said to having been developed during Russian space research at the secret radiological research laboratory at Obinsk near Moscow. Since then it has supposedly been successfully used on 300 cosmonauts and 30,000 cancer patients, in most cases as accompanying treatment to chemotherapy.

According to other sources, Galavit originates from a «proven American cancer therapy concept» (quote according to 14).
Studies
Medical databases do not currently contain any publications of case reports or clinical studies\(^5\,\^4\,\^7\), which substantiate the claims of suppliers with regard to the effectiveness of Galavit against cancer. Clinical studies are supposedly being prepared at present, which should meet the scientific standard\(^2\). Neither is there any data available regarding the safety of Galavit, which permits a judgement to be made\(^7\). At present both the Pharmaceutical Commission of the German Medical Profession as well as the German Cancer Society \(\text{[Deutsche Krebsgesellschaft e. V]}\) and the German Society of Oncology \(\text{[Deutsche Gesellschaft für Onkologie]}\) are advising against using Galavit due to a lack of information on the product. The German Society of Oncology considers the current use of Galavit to be purely profit-oriented rather than patient-oriented\(^15\).

Indications according to suppliers
The following indications are stated in the product information\(^2\): «Acute and chronic infections and inflammatory diseases, opportunistic infections, urogenital infections, autoimmune disorders, allergic inflammatory reactions, residual following traumatic and surgical operations, following radiotherapy, chemotherapy, immunosuppressive and corticosteroid therapy.» According to information on the package circular, Galavit can be used for «…correction of immunity in the pre- and post-surgical phase on cancer patients undergoing radio- and chemotherapy treatment…».

Contraindications according to suppliers\(^2\)
Pregnancy, incompatibility reactions

Side-effects/ adverse reactions according to suppliers
The information is of a contradictory nature: on the one hand, attention is drawn to the «increased effect on sexual power» in individual cases. Avoid simultaneous use of other immunostimulatory medicines\(^{12}\). On the other hand, according to the information on Galavit’s” package circular, there are neither known side-effects nor adverse reactions\(^{17}\).

Components/ Effect
2-amino-1,2,3,4-tetrahydrophthalazin-1-4 dione-sodium salt; there are at present no studies which prove the effect of this substance on cancer patients. The substance seems to be chemically very similar to luminol\(^{18}\), which is used in immunological detection diagnosis; in a chemical reaction it gives off light. Luminol dust can trigger allergies. The water-insoluble solution must be disposed in accordance with the directive on dangerous substances.

Manufacture/ Registration/ Legal position
The drug was registered by the Russian Health Ministry in 1997 as galavit phthalhydrosid salt. The Russian company MEDICOR manufactures and markets the drug. As far as the German Cancer Society is aware, the licensing procedure in Russia took place without the data being verified\(^7\). Both the sale and advertising of Galavit are prohibited in Switzerland. The drug is not registered at Swissmedic, the Swiss Agency für Therapeutic Products.

Dosage\(^2\)
One 100mg Galavit ampoule to be administered intramuscularly daily, for five days, then only every two to three days for three to four weeks, depending on the size and type of the tumour. Total number of injections recommended by the supplier: 15–20.
Costs
15 ampoules taken over a period of three weeks cost the equivalent of between around CHF 8,300 and 14,000\(^{1,2,14}\) depending on the supplier in Germany. Reporters were able to purchase the drug, without a prescription, for the equivalent of around CHF 17 per ampoule from a Moscow pharmacy.

Suppliers/ Patients
Mission Pharma AG, Basteiplatz 5, 8022 Zurich, www.galavit.at/Galavit/

References:
(1) www.galavit.de (Stand 2/2001)
(2) www.galavit.com (Stand 2/2001)
(3) www.galavitum.de (Stand 2/2001)
(4) www.vrzverlag.com/esoterik/legalavi.htm
(6) www.galavit.at/Galavit/index.html (Stand 8/2001)
(7) Stellungnahme der Deutschen Krebsgesellschaft e.V. zu «alavit»
(13) www.institut-harz.de
(14) Arzneitelegramm 11/00, Korrespondenz
(15) Zeitschrift für Onkologie 2000, 32/3:87: «... Die derzeitige Anwendungspraxis ist rein profitorientiert, nicht patientenorientiert!»
(16) Mitteilung der Arzneimittelkommission der deutschen Ärzteschaft, Deutsches Ärzteblatt 2001, 15: A1016
(17) Dr. B. Schmitt-Thomas, Deutsche Krebsgesellschaft e.V., pers. Mitteilung
(18) Der Arzneimittelbrief 4/2001, 35-29

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