Autologous platelet-rich plasma

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Executive summary

Health Council of the Netherlands

Especially in cosmetic and sports medicine, use is made of treatment with platelet-rich plasma made from the patient's blood (autologous PRP). The treatment is applied for a wide and expanding range of indications, where the goal is not always precisely defined. As a result of reports in the media about irresponsible use, the Health and Youth Care Inspectorate (IGJ) has taken enforcement actions. The Minister for Medical Care and Sports has asked the Health Council of the Netherlands to advise on the safety and quality of PRP treatment. He has also asked the board to examine whether the legal framework sufficiently guarantees safe application. The Committee on Quality and Safety of platelet-rich plasma has been set up to answer these questions.

Effectiveness and safety have not been proven

The Committee notes that there is as of yet little or no evidence of effectiveness for most applications of PRP. However, there is some evidencethat it has a beneficial effect for the treatment of tennis elbow, chronic wounds and in maxillofacial surgery. In general, however, the studies on which this evidence is based are small and the evidence is largely of medium to poor quality. Moreover, PRP can be prepared in many ways and there is no uniform product whose quality and safety are guaranteed for the patient. In practice, there appear to be no major complications associated with treatment using PRP. However, systematic research into side effects is lacking. Especially in view of the limited effectiveness of PRP treatment, the Committee believes that evidence for safety is of great importance.

Gapsin the legal framework

The legal status of PRP treatment differs among EU countries due to differences in the national implementation and application of European directives and regulations. In the Netherlands, autologous PRP treatment is not covered by relevans laws and regulations because the nature of the product does not or does not entirely comply with the definitions used. For example, PRP as a product does not fall under the regulations for the quality and safety of body materials and blood products. PRP can be regarded as a so-called *special need* medicine, which is permitted after approval by the IGJ; the enforcement of this regulation is complex. As a medical procedure, PRP treatment is currently covered by the Special Medical Procedures Act. However, the Committee does not consider this construction appropriate because platelets are not cells and therefore PRP administration does not fall under the definition of cell

transplantation. The Healthcare Quality, Complaints and Disputes Act (Wkkgz) may provide a basis to ensure the quality and safety of PRP treatment. This requires the existence of thorough guidelines and field standards that define good quality care. There are no solid guidelines and standards for this treatment at this time.

Recommendation

The Committee recommends encouraging solid, scientifically founded guidelines for the application of PRP so that quality monitoring can take place under the Wkkgz. Furthermore, it recommends investigating the extent to which the Medicines Act offers possibilities for monitoring the responsible use of PRP. It also recommends putting the shortcomings in legislation and regulations on the agenda at the European level.

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