

Grenz rays therapy for inflammatory skin conditions

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg236

1 Guidance

- 1.1 Current evidence on the efficacy of Grenz rays therapy for inflammatory skin conditions is very limited and is difficult to assess because reported patient groups are heterogeneous and patient numbers are small. With regard to safety, there is some concern about the risk of skin malignancy in the long term. Therefore, clinicians wishing to use Grenz rays therapy should do so only in research involving controlled trials, closely observed case series and/or contribution to a register. Studies should include clear definitions of treatment indications and quality-of-life measures.
- 1.2 Only carefully selected patients whose inflammatory skin conditions are unresponsive to other treatments should be offered Grenz rays therapy under the research conditions referred to in section 1.1.
- 1.3 The Institute may review this procedure in the light of further research.

2 The procedure

2.1 Indications

- 2.1.1 Grenz rays therapy has been used to treat many benign inflammatory skin conditions that have been unresponsive to conventional treatment, including some forms of eczema and psoriasis.
- 2.1.2 Treatment for inflammatory skin conditions depends on the type, severity and location of the inflammation. Topical treatments for eczema include emollients and non-steroidal immunomodulators. Non-topical treatments used for severe eczema that is unresponsive to other interventions include ultraviolet B (UVB) light therapy, psoralen with ultraviolet A (PUVA) light therapy and oral corticosteroids.
- 2.1.3 Topical treatments for psoriasis include emollients, keratolytics (salicylic acid), steroid creams and dithranol. Non-topical treatments include UVB light therapy, PUVA light therapy, retinoids and immunosuppressants. The Institute has produced guidance on a variety of treatments for eczema and psoriasis (see section 3.1).

2.2 Outline of the procedure

- 2.2.1 Grenz rays are a form of electromagnetic radiation, classified as 'ultrasoft' X-ray radiation, that are produced at low kilovoltages. The rays have a very low penetrative power and do not extend deeply into the dermis of the skin. A Grenz rays machine is used to direct radiation towards the affected area at a distance of approximately 10–20 cm. A cone can be used to restrict exposure to designated areas of skin and to maintain a constant distance. Patients are usually treated as outpatients over several short sessions, each lasting no more than a few minutes. Operators carrying out Grenz rays therapy for inflammatory skin conditions need to refer to 'The ionising radiation (medical exposure) regulations 2000' (see section 3.2).

2.3 Efficacy

- 2.3.1 In a randomised controlled trial (RCT) that compared Grenz rays with superficial X-ray treatment, 52% (13/25) of patients thought there was no difference between the treatments in improving the severity of their eczema 3 weeks after treatment, 44% (11/25) of patients considered superficial X-ray treatment to be better and 4% (1/25) considered Grenz rays to be better ($p < 0.05$). However, this difference was no longer significant at 18 weeks with 30% (6/20) of patients reporting superficial X-ray treatment to be better and 5% (1/20) reporting Grenz rays to be better. One RCT, which compared Grenz rays on one hand with a sham procedure on the other, reported no significant difference between Grenz rays and sham treatment, with 89% (16/18) of patients by observer assessment and 56% (10/18) of patients by patient assessment showing equal improvement in both hands 18 weeks after treatment.
- 2.3.2 Two RCTs compared Grenz rays treatment on one side of the head with a sham procedure on the other in patients with scalp psoriasis. In the first, complete healing was reported in 88% (14/16) of patients on the side of the scalp that received Grenz rays. No patients were reported to have better outcomes on the sham-treated side of the scalp compared with the Grenz-rays treated side. In the second, which studied patients with symmetrical psoriasis, Grenz rays therapy was reported to be superior to sham treatment in 67% (12/18) of patients, and 33% (6/18) of patients reported no difference ($p < 0.05$).
- 2.3.3 Three Specialist Advisers stated that Grenz rays therapy used to be widely used in the UK, but has been superseded by other forms of treatment. The Specialist Advisers highlighted uncertainties about aspects of the procedure, including optimal doses, number of exposures and dosing intervals.

2.4 Safety

- 2.4.1 A cancer registry linkage study reported that, among 14,140 patients treated with Grenz rays therapy and followed up for a mean period of 15 years, there were 39 observed cases of non-melanoma skin cancer, compared with 26.9 cases expected (ratio of observed and expected

cases = 1.45, 95% confidence interval [CI] 1.03 to 1.98). For more details, refer to the 'Sources of evidence' section.

- 2.4.2 The Specialist Advisers considered the main safety concern with Grenz rays therapy to be the potential for induction of skin cancer. They noted that other treatments for these conditions are also carcinogenic. Additional potential adverse events identified by the Specialist Advisers included erythema and pigmentation. The possibility of chronic radiation damage to the skin was also mentioned.

2.5 Other comments

- 2.5.1 Many of the published studies on Grenz rays therapy did not specify clearly their criteria for patient selection, or were carried out before several contemporary treatments became available (see sections 2.1.2 and 2.1.3).
- 2.5.2 The Specialist Advisers stated that Grenz rays therapy is usually reserved for patients whose inflammatory skin conditions have proved refractory to other treatments.

3 Further information

- 3.1 The Institute has issued technology appraisals on the [use of pimecrolimus and tacrolimus](#), and [topical steroids](#) for atopic dermatitis (eczema), and on [etanercept and efalizumab for the treatment of adults with psoriasis](#). A clinical guideline on atopic eczema in children is in development [Now published as '[Management of atopic eczema in children from birth up to the age of 12 years](#)'].
- 3.2 'The ionising radiation (medical exposure) regulations 2000', issued by The Department of Health and enforced by the Commission for Healthcare Audit and Inspection, should be referred to when radiation is used in a medical context. The equivalent regulations in Northern Ireland are 'The ionising radiation (medical exposure) regulations (Northern Ireland) 2000'.

Andrew Dillon
Chief Executive
November 2007

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document.

'Interventional procedure overview of Grenz rays therapy for inflammatory skin conditions', March 2007.

Information for patients

NICE has produced information describing its guidance on this procedure for patients and their carers ('Understanding NICE guidance'). It explains the nature of the procedure and the decision made, and has been written with patient consent in mind.

4 Changes since publication

The guidance was considered for reassessment in November 2010 and it was concluded that NICE will not be updating this guidance at this stage. However, if you believe there is new evidence which should warrant a review of our guidance, please [contact us](#).

14 January 2012: minor maintenance.

5 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE [interventional procedure guidance](#) process.

We have produced a [summary of this guidance for patients and carers](#). Information about the evidence it is based on is also [available](#).

Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).