Combined hormone replacement therapy (HRT) patient decision aid

What this decision aid is for

This decision aid is intended to assist health professionals in consultations with women who are considering taking combined (oestrogen plus progestogen) HRT. A separate decision aid is available relating to oestrogen-only HRT.

Benefits and harms of HRT

The MHRA published a review of the risks and benefits of oestrogen-only and combined HRT in September 2007. Healthcare professionals should refer to this for more detailed information. The MHRA advises that before prescribing HRT, healthcare professionals should assess carefully every woman’s overall risk, irrespective of her age or time since menopause and particularly in women older than 60 who have increased baseline risk of serious adverse events.

HRT effectively relieves vasomotor symptoms. It is also effective for prevention of osteoporosis, but its beneficial effect on bone diminishes soon after stopping treatment. In the review by the MHRA, combined HRT had no significant effect on the rate of femoral fractures among women taking it. The MHRA advises that, because of the risks associated with long-term use, HRT should be used for prevention of osteoporosis only in women who are unable to use other medicines that are authorised for this purpose.

These beneficial effects must be weighed against an increased risk of coronary heart disease (CHD), stroke, venous thromboembolism (VTE, i.e. deep vein thrombosis or pulmonary embolism), breast cancer and ovarian cancer. In women with a uterus, use of oestrogen-only HRT substantially increases the risk of endometrial hyperplasia and carcinoma. Addition of progestogen cyclically for at least 10 days per 28-day cycle greatly reduces the risk, and addition of progestogen every day eliminates the risk.

Technical note

The pictures on the next pages are a graphical representation of the data from tables in the MHRA review. They show what will happen to an average group of 1000 women who take combined HRT for five years. The first set relates to women aged 50 to 59 years, and the second set relates to women aged 60 to 69 years. Background incidence was taken from: Hospital Admissions in England (HES) for stroke and VTE; Women’s Health Initiative (WHI) trial for CHD; the International Agency for Research on Cancer (IARC) for ovarian cancer and endometrial cancer; and from never-users in the Million Women Study for breast cancer. Risk ratios and 95% confidence intervals were taken from: meta-analyses of randomised controlled trials (RCTs) for stroke; meta-analyses of RCTs and observational studies for VTE, endometrial cancer, and ovarian cancer; meta-analysis of RCTs and observational studies in Europe only for breast cancer; and from WHI trial for CHD. For any adverse effect, women at lower baseline risk will be less likely to experience that adverse effect, and women at higher baseline risk will be more likely to experience it. Full references are given in the MHRA review.

Reference

Imagine 1000 women aged between 50 and 59 years who take combined HRT for five years

Harms from combined HRT in women aged 50 to 59 years – cancer

These 10 women develop breast cancer but would have done so even if they had not used HRT

These 6 women develop breast cancer because they use HRT

These 2 women develop endometrial cancer but would have done so even if they had not used HRT. HRT does not cause any extra women to develop endometrial cancer

These 2 women develop ovarian cancer but would have done so even if they had not used HRT. HRT causes fewer than one extra woman in 1000 to develop ovarian cancer

These 980 women do not develop breast, endometrial or ovarian cancer, whether or not they use HRT
Harms from combined HRT in women aged 50 to 59 years – heart disease, strokes and venous thromboembolism (VTE, blood clots in the legs or lungs)

These 5 women develop VTE but would have done so even if they had not used HRT

These 7 women develop VTE because they use HRT

These 4 women have a stroke but would have done so even if they had not used HRT

This 1 woman has a stroke because she uses HRT

These 9 women develop coronary heart disease but would have done so even if they had not used HRT. HRT does not cause any extra women to develop coronary heart disease

These 974 women do not develop coronary heart disease, stroke or VTE, whether or not they use HRT

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Imagine 1000 women aged between 60 and 69 years who take combined HRT for five years

Harms from combined HRT in women aged 60 to 69 years – cancer

These 15 women develop breast cancer but would have done so even if they had not used HRT

These 9 women develop breast cancer because they use HRT

These 3 women develop endometrial cancer but would have done so even if they had not used HRT. HRT does not cause any extra women to develop endometrial cancer

These 3 women develop ovarian cancer but would have done so even if they had not used HRT. HRT causes fewer than one extra woman in 1000 to develop ovarian cancer

These 970 women do not develop breast, endometrial or ovarian cancer, whether or not they use HRT
Harms from combined HRT in women aged 60 to 69 years – heart disease, strokes and venous thromboembolism (VTE, blood clots in the legs or lungs)

These 8 women develop VTE but would have done so even if they had not used HRT

These 10 women develop VTE because they use HRT

These 9 women have a stroke but would have done so even if they had not used HRT

These 3 women have a stroke because they use HRT

These 18 women develop coronary heart disease but would have done so even if they had not used HRT. HRT does not cause any extra women to develop coronary heart disease

These 952 women do not develop coronary heart disease, stroke or VTE, whether or not they use HRT