

新一代光动力疗法（NGPDT）

患者须知

知情同意书

Patient Information and informed consent for Next Generation Photodynamic Therapy (NGPDT)

一、什么是新一代光动力疗法？

新一代光动力疗法（NGPDT）是 PDT 的最新阶段，它是癌症和多种医疗问题公认有效的疗法。与传统 PDT 治疗不同，它是一种全身性的治疗，它不仅能有效杀灭原发性癌症，而且能够杀灭转移扩散到全身的肿瘤。媒剂有口服和吸入两种给服途径，被血液循环系统吸收后会有选择性地积聚在肿瘤细胞内。然后通过特定波长的光激活光敏媒剂，释放单态氧，对有药剂积聚的癌症细胞进行破坏或杀灭。利用单态氧对癌细胞进行破坏，发生细胞结构分裂，继而入侵免疫细胞。使免疫细胞产生肿瘤特定抗体或‘疫苗’，抑制或控制在体内肿瘤的生长。

I. What is Next Generation PDT?

Next Generation PDT (NGPDT) is the latest development in PDT, an accepted and proven effective therapy for many types of cancer and other medical problems. Different from traditional PDT treatments, it is a systemic therapy and effective in not only killing primary cancer, but also metastatic spread of tumor throughout the body. Agent is administered orally or by inhalation and is absorbed into the bloodstream where it accumulates in tumour cells selectively. Following activation of Agent with a specific wavelengths of light, singlet oxygen is produced which is damaging or killing to cancer cells where the agent is concentrated. Singlet oxygen damage to the cells leads to the tumour cell structure fragmenting and subsequent invasion of cellular immune cells. These immune cells produce tumor specific antibodies or ‘vaccines’ which act to suppress or control tumor growth throughout the body.

访问以下网站，您可获得更多的信息：

如患者获得更多有关光动力疗法的丰富信息，请登陆以下的网站：

1. www.nextgenerationpdt.com
2. 第一代和第二代光动力疗法的相关信息以及光动力疗法概述，请登陆英国的网站：www.killingcancer.co.uk

More Information Available:

If patients are interested in obtaining more information about NG-PDT Therapy the following informative websites are available:

1. www.nextgenerationpdt.com
2. For information on the 1st and 2nd generation PDT and for general information about PDT from a UK site www.killingcancer.co.uk

二、新一代光子动力疗法的适应范围

新一代光动力疗法对各种恶性肿瘤细胞及变异的组织均有杀伤作用，适用于皮肤癌、鼻咽癌、喉癌、甲状腺癌、肺癌、食道癌、乳腺癌、胃癌、结肠癌、肾癌、肝癌、膀胱癌、直肠癌、子宫癌、血癌等，以及全身各部位原发性与转移性的恶性肿瘤。

II. Application of Next Generation PDT

NGPDT is active against many kinds of malignancy and abnormal tissue and has been shown to be effective against skin cancers, nasopharyngeal and cancers of throat, hypothyroid, lung, oesophagus, breast, gastric, colon, kidney, liver, bladder, rectum, uterus, leukaemia, and primary and metastatic malignant tumors in other parts of body.

三、新一代光动力疗法的特点

- 1、一种全身性的治疗，特别是对已发生转移或者被认定为不适合施行外科化疗和/或放疗手术的恶性肿瘤能够起到治疗作用；
- 2、治疗期间无手术、化疗、放疗所产生的副作用，是一种温和的疗法；
- 3、对没有药剂积聚的正常细胞不会造成损伤；
- 4、短期疗效是利用单态氧破坏肿瘤细胞，还具备对肿瘤的长期疗效，例如使肿瘤细胞自然凋亡、产生抗肿瘤抗体；
- 5、为了达到最佳疗效，特殊的病例可能需要施行多个疗程的治疗和/或做额外的处理；
- 6、光敏媒剂是一种从螺旋藻中提取的天然物质，它属有机微型藻类，世界许多国家批准作为食品补充剂。
- 7、透过体人免疫系统可产生肿瘤特异性抗体，有助控制体内肿瘤的生长。

III. Features of Next Generation PDT

- A. A systemic and effective therapy for malignancy which has already metastasized and is deemed unsuitable for surgery chemo and / or radiation therapy.
- B. A mild therapy with minimal side effects compared to surgery, chemo-therapy and radiation therapy.
- C. Harmless to normal cells where the agent has not accumulated.
- D. Destroys tumor cells with singlet oxygen in the short term and has long-term effects on tumors i.e. making the tumors shrivel naturally and generate tumor-specific antibodies.
- E. Extra procedures and / or more therapy may be helpful and necessary in some cases for maximum effect against some tumors.
- F. The Agent is derived from a natural substance extracted from spirulina platensis, an organic micro-alga approved in many countries around the world as a food supplement.
- G. Tumor specific antibodies may develop in patients with competent immune systems which help to control tumor growth throughout the body.

四、新一代光动力治疗期间的反应：

治疗期间，在肿瘤裂变过程中可能会出现以下症状：

- 1、疲乏感、类感冒症状，在肿瘤裂变部位伴有炎症和轻度疼痛及不适。
- 2、个别患者可能会出稍高的体温和盗汗的症状。
- 3、治疗后，肺癌患者可能会出现咳嗽。
- 4、消化道癌患者会出现轻度腹泻或由坏死肿瘤脱落而引起少量出血。
- 5、肿瘤所在部位会出现肿胀和炎症。

IV. Side Effects

Following the treatment and with the disintegration of tumor cells, the following side effects may appear:

- A. Feeling of tiredness, appearance of cold symptoms along with inflammation and slight aches and malaise in the area of disintegration of the tumors.
- B. Slightly high Temperature and night sweat may occur for individual patients.
- C. Cough may occur for lung cancer patients after receiving treatment.
- D. For the digestive system cancer patients, there may be some diarrhoea or slight bleeding due to necrotic tumor sloughing off.
- E. Swelling and inflammation in the area of tumor breakdown.

五、附加注意事项和建议：

- 1、在治疗时/后，均严格遵照医嘱接受治疗和护理；
- 2、治疗期间，不建议进行抗氧化剂治疗（包括不能使用维生素 C、维生素 E、过氧化物治疗、臭氧治疗）；
- 3、避免接种树突细胞疫苗；

V Additional Cautions and recommendations:

- A. Strictly adhere to the physicians' instruction during and after NGPDT therapy.
- B. Anti-Oxidant treatments is not recommended during the NGPDT course of treatment (this includes treatments with Vitamin C, Vitamin E, peroxide and ozone).
- C. Avoid treatments such as dendritic cell vaccine.

六、禁忌症：

- 1、卟啉病患者；
- 2、体弱患者；
- 3、孕妇；
- 4、肿瘤已侵入或包围（环绕）脊椎或主血管者；
- 5、黄疸患者（视起因而定）；

VI. Contraindication:

1. People who suffer from Porphyria;
2. Debilitated patients;
3. Pregnant women;
4. People whose tumour has invaded or encircles the spine or major blood vessels;
5. Jaundiced patients (depending on cause)

七、声明

- 1、医院不保证本疗法一定能够治愈患者全部的疾病。
- 2、必要时可根据可能患者的病情和疾病的类型，以及他们对治疗的反应情况提供一些治疗课程。
- 3、尽管 PDT 已被证实对多种癌症有效，但本院不保证该疗法一定能够治愈患者的疾病。
- 4、在对患者施行新一代光动力治疗前，本院已经对患者进行详尽的解释，对以上第七条所列情况引起的纠纷不承担任何法律责任。

VII. Disclaimer

1. *The Hospital* does not guarantee that the therapy will cure any diseases of the patients.
2. Several courses of treatment might be required depending upon the condition of the patient, the extent and type of disease as well as their response to treatment.
3. While this form of PDT has been shown to be effective in many types of cancer, *The Hospital* does not guarantee that this therapy will cure your disease.
4. The Hospital has carried out a thorough explanation to the patients before implementing Next Generation Photodynamic Therapy (NGPDT) to the patients, *The Hospital* does not bear any legal responsibility to dispute caused by circumstances described in clause VII.

八. 常规治疗流程

1. 为患者进行检查，在接受任何治疗之前我们将告知患者有关禁忌症。在患者接受治疗后，将按以下的步骤接受治疗：
2. 第一天：患者按照 1 毫克/千克体重的剂量服食光敏媒剂；
3. 第二天：采用光动力治疗床和激光治疗仪为患者进行照光治疗；
4. 第三天：经评估后，患者再次服食光敏媒剂；
5. 第四天：患者接受类似第二天的光照治疗；
6. 第五天：患者再次服食光敏媒剂；
7. 第六天：患者接受类似第二天的光照治疗。

由于每位患者的情况有所不同，故每位患者的治疗方案都会根据患者的具体情况进行适当的调整。

V111. A Typical Treatment Protocol

1. Patient is reviewed as to suitability and informed of any contra indications prior to any therapy application. On acceptance the patient will pursue the following;
2. Day 1. Patient is administered 1mg / kg bodyweight of photosensitive agent.
3. Day 2. The patient is administered light via our approved light delivery devices.
4. Day 3. Following review, patient is administered a re-supply of the photosensitive agent.
5. Day 4. Patient is given light treatments similar to day 2.
6. Day 5. Patient is administered agent (re- supply)
7. Day 6. Patient is administered light as in 2 above.

As every patient is different the protocol is duly mediated to suit individual requirements.

九. 新一代光动力疗法和老一代 PDT 的基本区别

1. 老一代光动力疗法（PDT）有许多不足，其中包括患者在治疗后必须避光以避免身体组织被光灼伤，而接受新一代光动力疗法（NGPDT）治疗的患者不再需要避光；
2. 由于老一代光动力疗法所采用的光敏媒剂的吸收峰所处波长较短，故其采用的光线的照射深度较浅，只能照射至体表浅层组织；而新一代光动力疗法（NGPDT）所采用的照射光线可照射入人体内部达 20 厘米深，从而首次实现了对人体内深层肿瘤进行非侵入性治疗及全身性治疗。
3. 因为老一代光动力疗法（PDT）需要借助介入式探头和内窥镜，故老一代光动力疗法（PDT）依然带有侵入性；而因为新一代光动力疗法（NGPDT）拥有深度激活能力，故无需再依赖任何过往的侵入性手段即可进行为患者提供有效治疗。

V1V. Basic differences between OLD PDT and NGPDT.

1. OLD PDT had many disadvantages, i.e. light exposure post administration had to be curtailed to avoid tissue burn. NGPDT has no such light sensitivity.
2. Agent properties only allowed for minimum depth of penetration of light due to its lower wavelength absorption. NGPDT allows for light penetration to depths of up to 20 cm's making the treatment of deep seated tumours a non-invasive reality for the first time, also making PDT whole-body therapy a possibility.
3. OLD PDT was invasive, using interstitial, probing and endoscopic procedures. NGPDT needs no such invasive procedures due to its deep activation abilities.

患者治疗同意书

姓名		年龄		疗程	
性别		诊断			
治疗前的身体情况					
<p>I. 请注意阅读以下 NGPDT 治疗须知:</p> <ol style="list-style-type: none"> 1、医院不保证本疗法能够治愈所有患者。 2、必要时可根据可能患者的病情和疾病的类型，以及他们对治疗的反应情况提供一些治疗课程。 3、尽管 PDT 已被证实对多种癌症有效，但本院不保证这种疗法能够治愈所有患者。 治疗期的长短将取决于病情和疾病的严重程度。 本疗法对多种癌症有效，但并不意味着或保证能够治愈。 <p>II. 请就是否接受治疗做充分考虑。并在做出决定之前，阅读所有资料以便能够充分了解所有事项。如果有任何疑问，或者需要澄清请及时提出。</p>					



请您在相应的选项中打“√”。

- 接受治疗
- 不接受治疗

患者签名： _____

家属签名： _____

日 期： _____

日 期： _____

Patient's Endorsement

Name		Age		Treatment	
Gender		Diagnosis		Period	
<p>Body condition before treatment</p>					
<p>I Please note that the following concerning NGPDT treatment:</p> <ol style="list-style-type: none"> 1. <i>The Hospital</i> does not guarantee that therapy will cure the disease of the patient. 2. Several courses of treatment might be required depending upon the condition of the patient, the extent and type of disease as well as their response to treatment. 3. While this form of PDT has been shown to be effective in many types of cancer, <i>The Hospital</i> does not guarantee that this therapy will cure your disease. <p>Length of treatment period will depend on patients' condition and severity of disease.</p> <p>This therapy is effective in many cancers but a cure is not guaranteed or implied.</p> <p>II Please give thorough consideration on whether to take our treatment or not. Read all data on the subject that is available, so as to be well informed prior to your decision. Any further questions opinions or clarifications needed will be promptly provided.</p>					



Please choose one of the following options with a“√”

- Accept Treatment
- Do not accept treatment

Patient's signature _____

Patient's family member's signature: _____

Date: _____

Date: _____

患者须知

在执行以上治疗方案时，可能会出现以下的若干现象：

1. 如果接受光照治疗后，患者出现明显的厌食症状，是正常反应。因为身体在这个期间正在吸取能量与坏死崩溃的肿瘤细胞搏斗，厌食症状是有效治疗的一种正常现象。
2. 在身体与坏死崩溃的肿瘤细胞搏斗期间，结合中药治疗是该疗法的主要组成部分。患者可以受益于著名的中国传统医药www.lamkamsang.com林淦生系列产品，林淦生系列产品是特别为新一代NGPDT制定的排毒和改善血液循环的产品。
3. 最后一次光照治疗结束后的10天到4周内，基于不同类型的癌症，患者普遍出现不同程度的发炎和疼痛症状，原因是患者免疫系统开始识别癌细胞并产生特定抗体去对抗癌症。
4. 如果肿瘤在器官上，会出现内出血症状，例如结肠癌，那是因为癌细胞迅速死亡并从健康组织中剥离，从而导致出血现象。出血现象为期2至4天，在粪便中可以观察得到。
5. 对于结肠直肠癌患者，从粪便中能看到剥落死亡的癌细胞污物，患者伴有经常性腹泻。
6. 患者必须注意的是对于大部分的病症来说，尽管一个疗程已经足够有效杀死癌细胞，但对于某些病症可能需要增加一个或更多的疗程进行治疗。
7. 所有患者必须注意在治疗期间和治疗后坚持运动锻炼的重要性。我们不推荐患者进行剧烈的严重消耗体力的运动，但进行一些患者认为力所能及和感觉舒适的常规锻炼是必须的。我们强烈推荐进行诸如步行、游泳或其它具有规律性而不剧烈的有氧运动。
8. 疲劳：患者必须了解在治疗期间和治疗后会有疲劳感的产生，那是由于体内供氧的需要和能量水平变动的的原因。

注意：

9. 疼痛：当肿瘤细胞瓦解的时候，身体的免疫系统和淋巴系统的能力负重，有时会导致发炎和短暂性的疼痛感增加。这种情况下，可以在主治医师的指导下服用一些抗炎药和/或止痛药。
10. 服用药剂前/后两小时，患者需要停止饮食（开水除外）。
11. 在治疗前和治疗期间，有可能需要用到氧气治疗，该部分只是疗程中的常规部分。

Patient Information

As the basic protocol is implemented, some of the following phenomena may be observed;

1. If a patient experiences a significant loss of appetite after light therapy, this should not be viewed negatively. The body at this time is conserving its energy to deal with the massive breakdown of tumour and loss of appetite can be a natural symptom of effective treatment.
2. The addition of Chinese herbal medicine is an integral part of this therapy when the body is challenged with the elimination of tumour breakdown. Patients with such challenges can expect to benefit greatly from the famous Chinese traditional Medicine Lam Kam Sang www.lamkamsang.com range of products especially formulated for Next Generation PDT in the removal of toxins and improvement in blood circulation.
3. It is commonly observed that patients get inflammation and pain depending on the type of cancer and the severity of disease 10 days to four weeks after the last light therapy, the patient's immune system begins to recognize the tumor and develop tumor specific antibodies to fight the cancer.
4. Internal bleeding can occur where a tumour is involved with organs, i.e. in colon cancer, as the cancer cells are dying so fast they can fall away from healthy tissue causing bleeding which can be observed in stools for periods of 2 to 4 days at a time.
5. In particular with Colon-rectal cancer, as the cancer breaks down discoloration can occur in stools, accompanied often times by diarrhoea
6. It is important for patients to note that whilst one therapy session is very powerful and highly effective in killing cancer tumour cells, **a second** or more treatment sessions may be necessary in some cases.
7. All patients should note the importance of movement / exercise during and after treatment therapy. Whilst it is not recommended to do rigorous exhaustive work-outs, it is essential to do regular exercise depending on the patient's ability and comfort. We strongly recommend walking, swimming or other aerobic exercise with more emphasis on regularity rather than volume.
8. Tiredness: Patients must be aware of the likelihood of tiredness during or after treatments as the demands on the bodies oxygen supplies and general energy levels fluctuate.

Note:

9. Patient to abstain from all food and drinks (except water) for 2 hours before and 2 hours after agent administration

10. Pain: As tumour masses break down, the body's immune system and lymphatic system capabilities are often stretched, sometimes causing inflammation and patients can experience a temporary increase in pain levels. Anti-inflammatory and or pain medication may be prescribed at the discretion of the attending or your own physician.

11. Depending on tests carried out prior to and during treatment oxygen may be required to be administered. This is a normal part of the procedure.

接受光动力疗法治疗的评估标准

尽管患者必须符合以下健康状况，以确保能获得最大限度的治疗效果，但患者不能因此认为该些就是最终决定标准。患者还应该向健疗医院/诊所的主治医师咨询清楚所有情况。

- 患者应该有足够的活力和有至少6个月较好的健康状况；
- 患者能活动自如（可独立行走）；
- 患者无须依靠输氧设备；
- 患者不能正在接受化疗、放射线治疗或服用抗生素进行治疗；
- 如果进行过手术的患者，必须先休息1到3个月再进行治疗；
- 该疗法不适合患严重黄疸病的患者；
- 该疗法不适合肿瘤细胞已经围绕或渗透进入脊椎的患者；
- 该疗法不适合孕妇；
- 尽管该疗法同时适合年幼患者，患者的年龄在18岁以上为最佳。

General Criteria for Selection of Patients suitable for NGPDT:

- Patient should have enough vitality and have at least 6 months of reasonable health available to them.
- Patient should be ambulatory (walk unaided)
- Patient should not need an artificial oxygen supply.
- Patient should not be on chemotherapy or radiation or any other immune suppressant drugs.
- Patient should allow a time lapse of 1 to 3 months since last major surgery.
- Patient should not suffer from porphyria or other skin light sensitive conditions.
- Patients should not suffer with severe jaundice.
- Patients with tumors involving a major blood vessel where treatment may lead to major hemorrhage can be very problematic.
- Patients with tumor surrounding or infiltrating the spinal column may be unsuitable.
- Patient should not be pregnant.
- Although younger patients have been treated, it is preferred that patient be over 18 years old.

信息披露/药物治疗

任何患者自己采取的药物治疗必须先经过新一代光动力医院的检查许可。药物治疗包括服用各种维生素、矿物质或荷尔蒙激素补充物。在治疗开始前，患者向诊疗中心公开所有的药物治疗、处方药物、非处方药物以及营养补充药物，这对医师优化选择治疗方案和开始后续的治疗程序是非常关键的。

Disclosure / Medications:

Any and all self-medication programmes need to be checked with the Next Generation PDT hospital / clinic. This includes all vitamin, mineral or hormonal replacement supplements. At the centre full disclosure of all medication, prescription, non-prescription and recreational drugs prior to commencement of therapy is absolutely essential to optimise the individual treatment protocol and for subsequent data processing.

NGPDT 知情同意书

本人承诺如下：

本人已经仔细阅读了医院提供的所有新一代光动力疗法（PDT）资料 and 文件。

本人评估了接受光动力疗法后的风险和可能产生的副作用，并同意承担这些风险。如果对所有治疗方面的不确定性，本人需要求 NGPDT 治疗中心作进一步的解释。

本人已经权衡各种癌症的治疗方法，包括手术，化疗，放射治疗，激素治疗，免疫治疗以及 PDT 治疗，在不受任何外界影响的情况下，本人决定接受 PDT 治疗。

本人知道 PDT 是一种新型的、发展中的 21 世纪癌症疗法。

假如本人是女性，在接受 PDT 治疗时必须避免怀孕；如果怀孕，可能会导致胎儿先天严重缺陷或死亡。

医疗资料披露同意书

本人知道医院并不保证或声明 PDT 癌症疗法一定能成功治愈癌症，或者一定能够提供任何疗效；在接受 PDT 治疗后，产生的任何伤害，副作用，损失或损害，或者由医院提供的资料，在法律允许的范围内，医院将不承担责任。

本人同意参加 PDT 治疗，并同意提供本人的健康信息作为记录保存及新一代光动力疗法的进一步发展，但所有这些资料以及统计数据必须经由医院确定后，才能向第三方披露。

本人已阅读并理解的本资料中的所有信息以及其他提供的文件，其中包括 PDT 疗法及其排除条件。

患者签名：	
姓名：	
日期：	
NGPDT 首席医疗官：	
姓名：	
签名：	
日期：	
医生见证人：	
签名：	
姓名：	
日期：	

NGPDT Informed Consent Form

I acknowledge the following:

That I have carefully read the information and documentation provided to me about Next Generation Photodynamic Therapy (PDT).

That I have evaluated the risks and possible side effects as a consequence of undergoing PDT and agree to personally bear these risks. If I am uncertain about any aspect of the Therapy, I acknowledge that I can obtain further clarification from The NGPDT treatment centre.

That I have reviewed and carefully considered various cancer treatments, including surgery, chemotherapy, radiotherapy, hormonal therapy and immunotherapy as well as PDT and I have made my decision to pursue PDT myself, free of any outside influence.

That I understand that PDT is new and developing cancer treatment for the 21st Century.

That if I am female, I must avoid pregnancy whilst receiving the PDT, as any failure to do so, may cause serious birth defects or death to a fetus.

MEDICAL DISCLOSURE & CONSENT FORM

I acknowledge that The Hospital does not warrant or represent that PDT is a cure for cancer or that it will be successful or provide any benefit whatsoever and to the extent permitted by law, the Hospital cannot be held liable for any injury, side effect, loss or damage incurred as a result of receiving PDT or from reliance on the information provided by The Hospital, whether arising from strict liability, negligence or otherwise.

I consent to participate in the PDT treatment, to allow collection of health information relating to me for record keeping and it being used for the improvement of NGPDT cancer treatment technology, provided however that all such information is de-identified by The Hospital prior to it being released to any third parties.

I acknowledge that I have read and understand the information contained in this form as well as the other documentation provided to me, which includes information about PDT and exclusion criteria for PDT.

PATIENT SIGNATURE :	
NAME :	
DATE :	
NGPDT - Chief Medical Officer :	
SIGNATURE :	
NAME :	
DATE :	
DOCTOR WITNESS :	
SIGNATURE :	
NAME :	
DATE :	